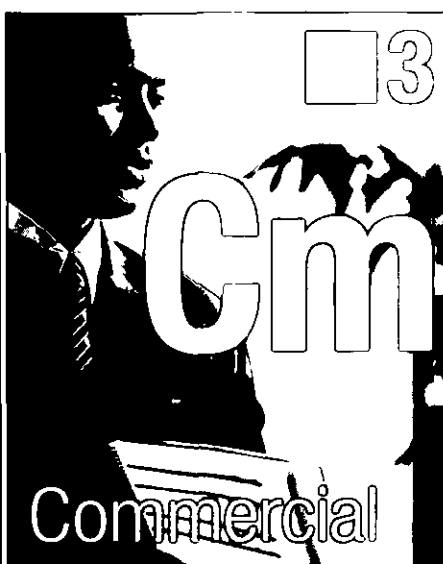




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Building on the  
Elements of Success.



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## Our Mission Statement:

Sepracor is dedicated to discovering, developing and commercializing innovative pharmaceutical products and services that improve health and quality of life. We understand our responsibility to ensure that decisions are guided first and foremost by what is in the best interests of patients. We are committed to the welfare of the patients we serve, the success of our employees and to increasing shareholder value.

### CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This annual report to stockholders contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to the safety, efficacy and potential benefits of our products and products under development, expectations with respect to the timing and success of regulatory filings, the development and commercialization of our products and product candidates and acquisitions of technologies, product candidates, approved products and/or businesses, the scope of patent protection with respect to our products and product candidates and other plans and strategies. All statements other than historical facts included in this report are forward-looking statements. When used in this report the words "expect", "anticipate", "intend", "plan", "believe", "seek", "will", "estimate", "goal", "should" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this report. The forward-looking statements contained in this annual report represent our expectations as of the date of this report and should not be relied upon as representing our expectations as of any other date. Although subsequent events and developments will cause our expectations to change, we specifically disclaim any obligation to provide updates.

All market data and share calculations contained in this report are sourced and derived from IMS Health Incorporated information.

**ERRATA**  
**SEPRACOR 2007 FORM 10-K**

The number of shares of common stock reported as outstanding on the cover page of the Sepracor 2007 Form 10-K contained herein incorrectly includes treasury shares. The correct number of shares of Sepracor common stock outstanding as of February 15, 2008 was 107,769,736.

## The Meaning of Our Elements

As in pharmacologic chemistry, when seemingly disparate elements combine, a favorable reaction can take place whose sum outcome is greater than any of the individual elements from which it is composed. Such is the case with Sepracor's business model. Within the pages of this year's annual report, we have defined the individual elements that are crucial to the ongoing success of the company. While each is critically important in its own right, it is within the context of our overarching goal of enduring success that the effective integration of these elements becomes vital.

The elements of our planned success include sustaining peak financial performance, developing partnerships to leverage opportunities for growth, building market share through our expanding portfolio of commercial products, harnessing the strength of our infrastructure to discover new drug therapies for tomorrow and channeling the passion of our employees' commitment to improving health through innovation. These elements are the measure of our ability to increase value for our shareholders, partners, employees and, most fundamentally, for the patients whose good health is the ultimate focus of our collective efforts.

## To Our Shareholders:

In March 2007, I joined Sepracor as President and Chief Operating Officer. I then assumed the role of Chief Executive Officer in May 2007. I had been familiar with Sepracor for many years prior to joining, and it was a company for which I had a great deal of respect and admiration. I had watched its accelerating growth over the years and, like many, recognized this company as having great potential in the specialty pharmaceutical industry, with a very attractive, but evolving, business model. This model encapsulated a fully integrated infrastructure, the flexibility and power of its primary care and specialty commercial emphasis, its growing, yet focused, pharmaceutical pipeline and the depth and experience of its talented and professional work force. It was all of these qualities, combined with what I saw as the company's potential, that made me proud to be able to join this organization. I saw before me the opportunity to build the company to its next level and to work to position it as one of the most successful specialty pharmaceutical companies of the next decade – in essence, to create and implement a compelling vision resulting in a potentially tangible and successful reality for all of Sepracor's stakeholders.

Sepracor has a proud and strong heritage, one that was formed by the determination of its founders and people, together with what was then a unique platform in drug development. Sepracor was built on the premise that chiral drugs could, in essence, be divided into two or more "parts" and that certain of these parts could be brought to the market as new medicines with the possibility for reduced side effects, greater potency or new indications. Not only did the company prove that this could be done, but Sepracor was a pioneer in this area of drug development, identifying new, viable compounds long before others in the field recognized the validity of this approach and began developing their own compounds through chiral chemistry. This strategy enabled Sepracor to establish itself initially by out-licensing the rights to a number of compounds to large, established pharmaceutical companies who developed and ultimately commercialized them. These products have grown to become well-known brands in the pharmaceutical

industry: ALLEGRA® brand fexofenadine HCl, CLARINEX® brand desloratadine and XYZAL®/XUSAL™ brand levocetirizine.

During the last decade, Sepracor evolved into a fully integrated, research-based pharmaceutical company that launched its first self-developed and self-commercialized product, XOPENEX® brand levalbuterol HCl Inhalation Solution, in 1999. By the end of 2007, Sepracor had grown into a company with more than \$1.2 billion in revenues, three additional products – LUNESTA® brand eszopiclone, XOPENEX HFA® brand levalbuterol tartrate Inhalation Aerosol and BROVANA® brand arformoterol tartrate Inhalation Solution – and nearly 2,300 employees with its own broad-based sales force and full research and development organization. It is my privilege to be a part of this organization and to be in a position to help take the company through its next stage of evolution.

At the beginning of 2007, we had an exceptionally strong platform that included three commercialized products and an experienced sales force and research and development organization, including an increasingly productive discovery team focused on identifying new compounds to bring into the clinic. All of these strengths form a solid base for our future growth. When I joined the company last year, the Board of Directors charged me with the tasks of building from the great successes achieved under the company's founder, visionary and then-Chief Executive Officer, Timothy Barberich, and shaping the company for its next phase of growth. This future growth will be based on a global corporate strategy of fully leveraging our existing and new product franchises, driving enhanced research and development productivity and successfully pursuing aligned and value-enhancing corporate development and licensing initiatives. In 2007, we made great strides toward accomplishing each of these objectives despite some significant challenges. Nevertheless, there is more to be done, and I am very confident in this organization's capability in meeting and exceeding expectations over time and creating enhanced shareholder value.

## EXCELLENCE IN PORTFOLIO COMMERCIALIZATION

During 2007, market share and revenues for our products did not develop as robustly as we had hoped due to a number of factors, including challenges from competitors, generic entrants and government reimbursement changes. Recognizing this, we have begun to take steps that we anticipate will reinvigorate growth of our XOPENEX HFA, LUNESTA and BROVANA products.

As part of our objective to create a stronger and more productive commercial organization, we appointed several new senior managers to key strategic and operational roles within the commercial function during the second half of 2007 and streamlined and realigned our sales organization – key steps toward developing best-practice and peak-performing commercial capabilities. Designed to improve physician targeting, resource allocation, incentives, efficiency and productivity, we believe that the sales force realignment will enhance sales call productivity and provide a solid sales force footprint as we explore opportunities to expand our sales capacity in 2008 and beyond in support of our growing commercial product portfolio. To achieve commercial excellence, we expect to leverage all aspects of sales force education and promotion and foster a powerful climate of accountability. We realize that our sales force is, and will continue to be, fundamental to our business and is at the center of a productive commercial organization. We believe that these alterations to our commercial infrastructure form the foundation for, and should provide our sales professionals with, the tools with which to build excellence and a stronger, more productive commercial organization – they, our shareholders, our products and our patients deserve that.

## DELIVERING TOMORROW'S MEDICINES

During the past year, our research and development group made tremendous progress, advancing several earlier-stage clinical candidates and introducing new lead compounds from our discovery efforts to clinical studies.

In all, we advanced five clinical compounds during 2007. SEP-225289 and SEP-225441 both advanced to Phase II studies for the treatment of depression and anxiety, respectively, and SEP-227162, also for the treatment of depression, is anticipated to

begin Phase II/III in 2008. We also achieved a milestone in 2007 with a transition from our roots in drug development through chiral chemistry to an enhanced focus on the discovery and development of potentially ground-breaking new chemical entities derived from our own discovery research. Among our new candidates are SEP-228425 and SEP-228432, both for depression, for which we filed Investigational New Drug (IND) applications at the end of 2007 and for which we expect to conduct clinical studies in 2008.

Our pipeline of pharmaceutical candidates is a significant component of our future growth strategy, and an essential part of our research and development function will be continued development of value-enhancing collaborations, to ensure that we utilize the most cost-effective resources on a worldwide scale. During the year we formed collaborations with PsychoGenics for access to their proprietary behavioral pharmacology technology; ChemPartner and PharAdvance, both based in China, for their synthetic chemistry resources; and Scottish Biomedical of the European Union (EU) for drug lead generation. With the potential for additional product launches from our proprietary pipeline in the coming years, we believe we have positioned ourselves for steady, organic growth, the introduction of new medicines for the treatment of prevalent diseases and conditions and ultimately, enhancing shareholder value.

## SUCCESSFUL CORPORATE DEVELOPMENT AND LICENSING

Corporate development and licensing initiatives are a fundamental part of our growth strategy, creating a bridge to our earlier-stage pharmaceutical candidates and positioning the company for ongoing sales growth, a deepening pipeline and expanding our therapeutic reach. If successful, these evolving initiatives may also help minimize the impact of future patent expiries encompassing certain of our core products. In the second half of 2007 and in early 2008, we successfully completed a total of four significant agreements. The first of our successes was a partnership with Eisai Co. Ltd. (Eisai) to develop and commercialize our insomnia product, eszopiclone, for the Japanese market. This represented the first advancement in expanding Sepracor's proprietary products to worldwide markets, and we view it as a significant step forward. We quickly followed this partnership with an alliance with GlaxoSmithKline (GSK) for commercialization of eszopiclone



worldwide in all countries except the U.S., Canada, Mexico and Japan. We believe that both of these alliances provide the optimal launch platform from which to introduce eszopiclone worldwide, turning our scientific innovation into a global commercial reality.

In late 2007, we in-licensed a new Phase III product to add to our portfolio. Through an exclusive licensing agreement with Bial-Portela & C<sup>a</sup>, S.A. (Bial), a privately held Portuguese pharmaceutical company, we acquired the rights to commercialize its anti-epileptic compound, BIA 2-093 (eslicarbazepine acetate), in the U.S. and Canada. Phase III studies of BIA 2-093, which we now refer to as SEP-0002093, have been conducted and completed by Bial. The addition of this new epilepsy treatment to our product portfolio serves to expand our central nervous system (CNS) franchise and strategically provides a bridge from our currently commercialized products to our Phase II compounds that are focused on the treatment of CNS disorders, including anxiety, depression and pain.

In January 2008, we completed the acquisition of exclusive distribution rights to two new, commercialization-ready products

for asthma and allergic rhinitis. In an alliance with Nycomed GmbH (Nycomed), a European pharmaceutical company, we gained the rights to develop, market and commercialize ALVESCO<sup>®</sup> HFA (hydrofluoroalkane) brand ciclesonide Inhalation Aerosol and OMNARIS<sup>™</sup> AQ (aqueous solution) brand ciclesonide Nasal Spray in the U.S. We believe the addition of these products to our commercial portfolio is highly synergistic with our proprietary respiratory franchises and further leverages our commercial infrastructure, capabilities and established customer relationships. In addition to these two U.S. Food and Drug Administration (FDA)-approved products, we also obtained the rights to develop several line extensions, which have the potential to further broaden our respiratory portfolio. These programs include OMNARIS HFA metered-dose inhaler (MDI), a Phase II candidate; ciclesonide inhalation solution, a preclinical candidate; and ciclesonide in combination with a long-acting beta-agonist, an early clinical candidate. In our view, the addition of these new products and product candidates should add significant value to our commercial and research and development organizations.

## SUSTAINED PEAK FINANCIAL PERFORMANCE

Our financial results for 2007 reflected various business challenges and opportunities that we faced during the year, including a reduction in the reimbursement rate for XOPENEX Inhalation Solution under Medicare Part B, introduction of a generic competitor to the insomnia therapeutic category, the effects of litigation settlements and the successful completion of significant in- and out-licensing transactions. Importantly, and despite these challenges, total revenues for the year were the highest in our history at more than \$1.2 billion. We also concluded the year with nearly \$1.1 billion in cash and short- and long-term investments, providing us with added flexibility to pursue other value-enhancing opportunities in 2008, and positioning ourselves for business growth and increased shareholder value into the future.

## MAKING A DIFFERENCE THROUGH PEOPLE

We have charted our course with the successes of 2007 and early 2008 and have focused and aligned objectives for the remainder of 2008. In our commercial organization, we expect to emphasize recruitment, retention and employee development and execute

with what we view as our new and more productive sales force structure. Fully leveraging our commercialized products and successfully launching our newly acquired products, OMNARIS AQ and ALVESCO HFA, will be a focus of our commercial organization this year. In research and development, we expect to advance our preclinical and clinical candidates and devote significant resources to successfully submitting a New Drug Application (NDA) for SEP-0002093, our newly in-licensed and exciting anti-epileptic product, by the end of the year or in early 2009. We also expect to continue to pursue strategic corporate development and licensing opportunities. These agreements may include in-licensing additional compounds for development and commercialization, co-development collaborations, consideration of appropriate merger and acquisition activities and further expansion of discovery efforts through tactical collaborations. We will remain an opportunistic but focused organization.

We have what promises to be a busy but exciting year ahead of us in terms of strengthening capabilities and successes in research and development, commercial development and licensing and commercial execution, and I am confident in our prospects. We have established a clear vision of our future, and have aligned ourselves for significant growth in the years ahead with seven potential product launches between 2009 and 2014. It is important to note the role that our employees have had, and will continue to have, in making all of this possible. Without employees who possess strong values and ethics and a unifying commitment to improving health through innovation, we would not be where we are today. My thanks and appreciation go to each and every one of our dedicated employees. I look forward to reporting our progress to all of our stakeholders – patients, physicians, employees and shareholders – throughout the year.

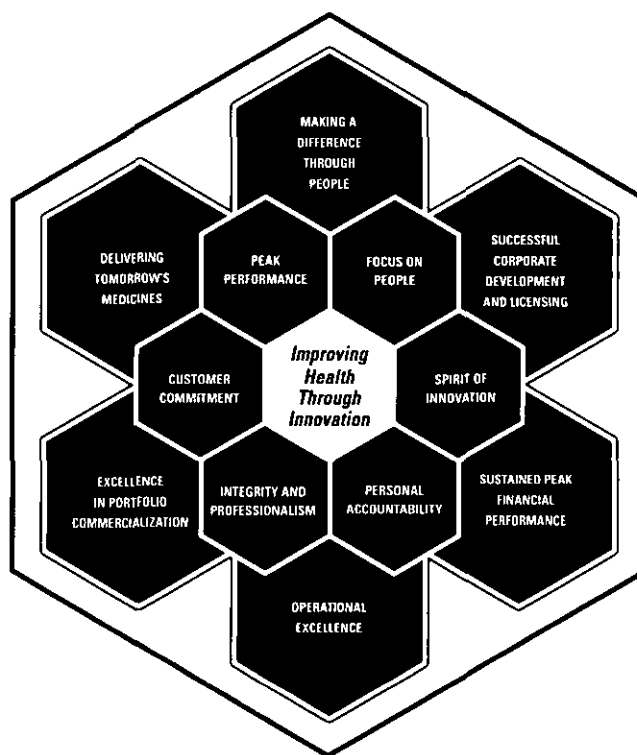
Sincerely,



Adrian Adams

President and Chief Executive Officer

## Improving Health Through Innovation



We believe that our success is predicated on discovering, developing and commercializing novel pharmaceutical therapies that will meet underserved market needs. Our continued ability to do so will be enabled by committing to the achievement of identified strategic goals and embracing a defined set of values that drive this commitment. Our belief system was developed by employees across our organization and is shared by all; at its core is our underlying dedication to **Improving Health Through Innovation.**





Financial

## The Performance Element

# Driving sustained peak financial performance enables us to build a foundation for the future.

One of our business goals at Sepracor is to drive peak financial performance by meeting or exceeding our earnings projections through overall revenue growth and from prudent and judicious cost management. By delivering healthy financial performance through improved cost structures, we have greater capacity to develop and commercialize breakthrough medicines for those patients who need them, which in turn has the potential to provide greater shareholder value.

In 2007, we continued our track record of delivering increasing revenues, with total revenues reaching the highest level in our history at more than \$1.2 billion – a 3.6 percent increase over the prior year. These revenues were driven principally from sales of our proprietary products, with the greatest contributions coming

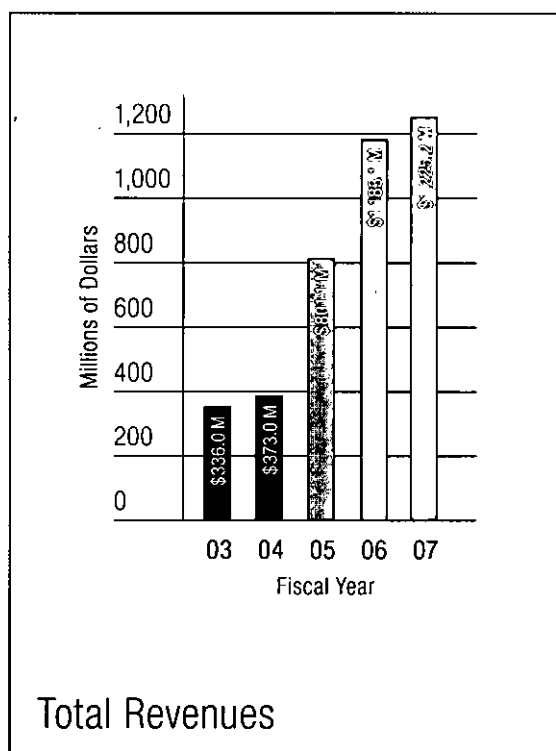
from our LUNESTA and XOPENEX product franchises. XOPENEX franchise revenues were \$562.1 million, \$487.2 million of which were derived from sales of XOPENEX Inhalation Solution and \$74.9 million from sales of XOPENEX HFA. LUNESTA, our insomnia medication launched in 2005, achieved \$600.9 million in revenues during the year, and we expect the product to continue to be a significant contributor to overall revenues in 2008 and beyond.

Launched in April 2007, BROVANA had revenues of \$14.3 million in 2007. It is our belief that revenue contribution from this product will increase in 2008, facilitated, in part, by easier reimbursement through Medicare Part B.

Supplementing our proprietary product revenues were royalties earned on sales of products for which we have out-licensing agreements, including sanofi-aventis' ALLEGRA, Schering-Plough's CLARINEX and UCB Pharma's XYZAL/XUSAL. Total royalty revenues in 2007 were approximately \$48 million.

Early in 2007, we improved our debt position by repaying \$440 million of our total outstanding debt, and we closed the year with approximately \$721 million in remaining outstanding convertible debt. We also finished the year with a very strong position in cash and short- and long-term investments at almost \$1.1 billion, providing us with continued flexibility to pursue potential product in-licensing, acquisition or other business expansion opportunities.

As we continue to grow and generate revenues from our marketed products, we expect to reinvest a significant portion of these revenues into areas that we feel will contribute most significantly to future growth, including research and development and corporate development and licensing initiatives. Emphasizing sustained peak financial performance should provide us with the financial leverage necessary to enable us to enter into strategic partnerships and advance our clinical assets, with the goal of ultimately enhancing shareholder value.





200

Corporate  
Development

## A Growth Element

# Creating opportunities for growth through strategic corporate development and licensing.

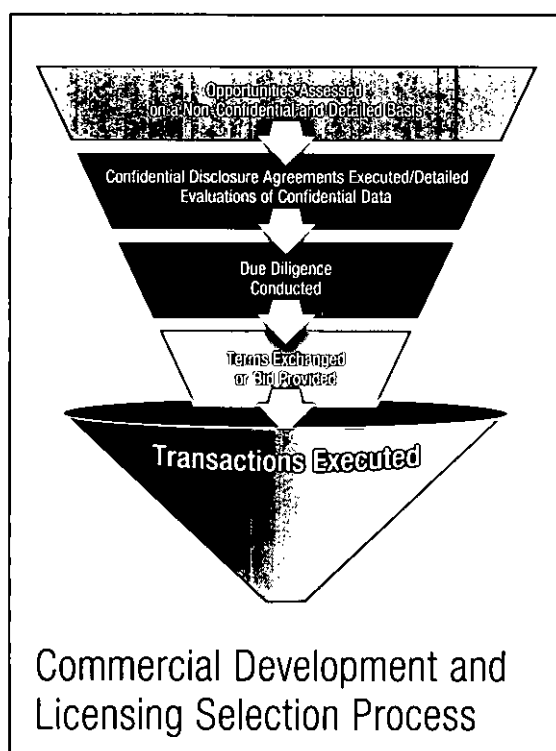
We believe our overall global corporate strategy to fully leverage our product franchises and commercial infrastructure makes us a natural partner of choice for foreign and domestic pharmaceutical companies. We also believe that our fully integrated infrastructure – the company's capacity to discover, develop, successfully navigate an NDA through the FDA and ultimately commercially launch and market new medicines – is appealing to companies seeking to maximize, develop or launch their assets in the U.S. market. Our experienced research and development organization has the capability to advance a compound from any stage of development, which is an attribute that should be of value to

earlier-stage companies that lack the necessary infrastructure or expertise to develop products in the U.S. Similarly, we believe that our commercial organization's size and access to the primary care and specialty marketplaces make us an attractive partnership alternative to multinational pharmaceutical firms for those seeking to commercialize new products in the U.S. market.

Early in its history, Sepracor focused on out-licensing rights to single-isomer and active-metabolite formulations of established pharmaceutical products. Today, in addition to discovering and developing proprietary novel compounds, Sepracor's global strategy includes the successful pursuit of aligned and value-enhancing corporate development and licensing initiatives. This is an area in which we have recently made meaningful strides. We completed four significant corporate development transactions over the course of 2007 and early 2008, two of which were with European pharmaceutical companies seeking to capitalize on our development and U.S. commercialization capabilities.

### ESZOPICLONE WORLDWIDE

During the year, we made significant advances in introducing our eszopiclone product (sold in the U.S. under the brand name LUNESTA) to international markets, beginning with the establishment of a partnership with Eisai in July 2007. Eisai's long-proven development capabilities, especially in the



CNS therapeutic area, as well as its commercial infrastructure, provide us with what we believe will be an optimal launch platform from which to expand our LUNESTA franchise to the Japanese marketplace. Under this agreement, Eisai will conduct clinical trials of eszopiclone in Japan and, contingent on successful completion of these studies, apply for marketing approval from the Japanese regulatory authority to commercialize the product in Japan. Estimated to be valued at approximately \$500 million, with 24 million Japanese believed to suffer from insomnia, the Japanese marketplace represents a sizeable opportunity into which to introduce our insomnia medication.

Also during the second half of 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product worldwide in countries other than the U.S., Canada, Mexico and Japan. GSK has a strong presence in the EU and other global markets, with extensive experience in the CNS therapeutic area. Sepracor submitted a Marketing Authorization Application, which is the equivalent of an NDA in the U.S., to European regulatory authorities early in the second half of 2007, and we are targeting EU regulatory approval at the end of 2008. Successful approval of our eszopiclone product in the EU should enable our partner, GSK, to commercially introduce the product as LUNIVIA® brand eszopiclone shortly thereafter.

#### SEP-0002093

In December 2007, we entered into an exclusive agreement under which we obtained the rights to commercialize an anti-epileptic agent in the U.S. and Canada from Bial. Phase III studies of the compound, which Bial refers to as BIA 2-093 and which we now refer to as SEP-0002093 (eslicarbazepine acetate),



Acquiring early-, middle- or late-stage pharmaceutical candidates and products is one of our strategies for growing our business. Our approach to product acquisitions and licensing is based not only on identifying candidates that we believe are synergistic with our established products and business model, but which have the potential to treat some of the world's most prevalent diseases and conditions and improve patient quality of life.

have been completed. We have begun to assemble an NDA for submission to the FDA, which we are targeting for late 2008 or early 2009. In clinical studies, once-daily SEP-0002093 demonstrated clinical efficacy in controlling seizures when used as adjunctive therapy, offered simpler dosage titration and was well tolerated.

Contingent on FDA approval, we would expect to commercialize SEP-0002093 through our CNS specialty field force, focusing on neurologists and epileptologists, who are the principal prescribers of anti-epileptics.

## THE CICLESONIDE PRODUCT FRANCHISE

We continue to vigorously pursue strategic partnerships that we expect will provide significant growth opportunities for our business, and in January 2008, we successfully acquired the exclusive distribution rights to the ciclesonide product franchise for the U.S. market from Nycomed. Significantly, this agreement includes the rights to two FDA-approved products: OMNARIS AQ for allergic rhinitis, which we expect to commercially introduce in April 2008, and ALVESCO HFA, an inhaled corticosteroid for the treatment of asthma, which we intend to launch during the second half of 2008. The ciclesonide franchise complements our respiratory portfolio and further leverages the company's commercial infrastructure, customer contacts and capabilities.

This agreement also provides Sepracor with development rights to line extensions, which have the potential to expand Sepracor's existing pharmaceutical pipeline. These line extensions include: OMNARIS HFA, an MDI Phase II candidate; ciclesonide inhalation solution, a preclinical candidate; and ciclesonide in combination with a long-acting beta-agonist, which is an early clinical candidate.

This highly synergistic agreement with Nycomed provides Sepracor with commercialization-ready respiratory products that should help to grow total revenues for 2008 and beyond as well as candidates that enhance Sepracor's existing respiratory portfolio. With a proven sales force that has significant experience in promoting Sepracor's proprietary respiratory products, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA, OMNARIS AQ and ALVESCO HFA are logical additions to our respiratory portfolio.

Throughout 2008 and beyond, we expect to continue to seek value-enhancing corporate development and licensing opportunities that are opportunistic, entrepreneurial and are in, what we believe to be, our shareholders' medium- to long-term interests. These opportunities may include in-licensing currently

marketed products or Phase II or Phase III clinical candidates that are synergistic with our existing marketed products and pharmaceutical pipeline, expanding our global footprint, assessing compounds under development within or outside of the U.S. that may enable us to enter new therapeutic areas, assessing appropriate merger or acquisition opportunities and/or establishing discovery collaborations to identify new lead candidates.



According to the Allergies in America survey, a landmark survey of nasal allergy sufferers, more than 14% of adults in the U.S. reported having been diagnosed with nasal allergies. An estimated 40 million Americans are affected by allergic rhinitis.

## The Commercial Element

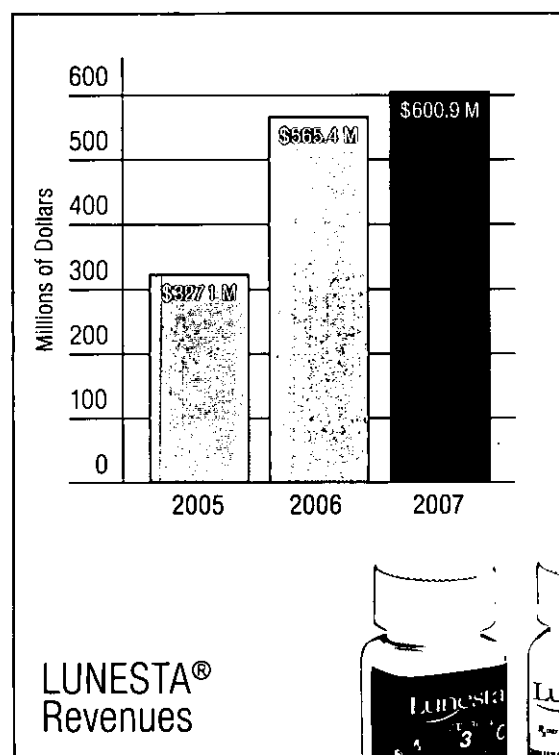
# Expanding our commercial franchises by focusing our presence in targeted markets.

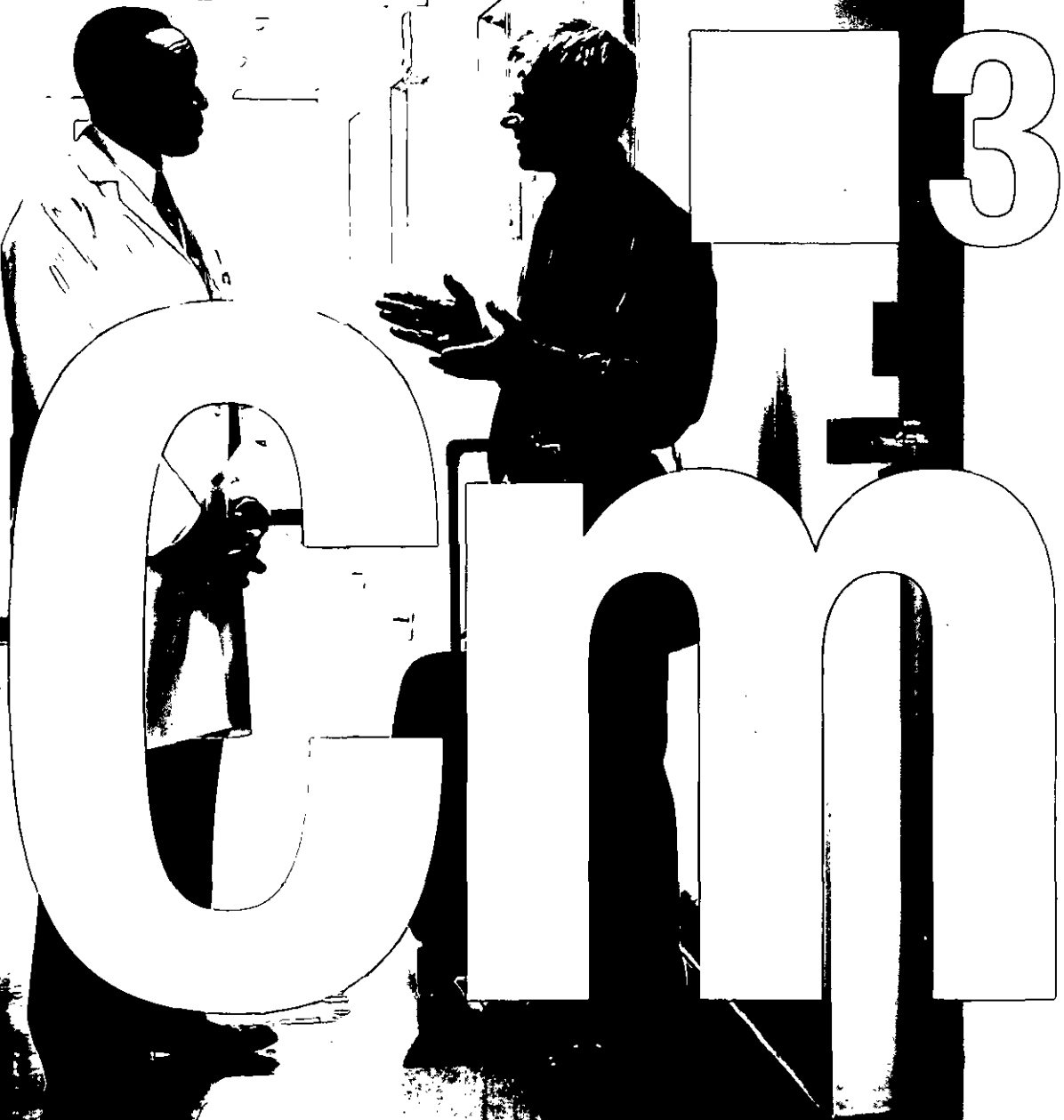
Our commercial philosophy encompasses the pursuit of peak performance with a focus on creating opportunities and maintaining and cultivating high-quality interactions with our valuable customers and opinion leaders. Part of our mission is commercial execution supported by strong ethics and accountability, using all appropriate educational and promotional resources available to communicate the attributes of our products to patients and physicians alike. To accomplish this, we rely on physician education from sales professionals and medical liaisons, publication and presentation of study results in scientific journals and medical society meetings through our experienced medical affairs organization and through appropriate direct-to-consumer promotion.

As part of our commitment to commercial excellence, we implemented a sales force realignment during the fourth quarter of 2007. This realignment was instituted to optimize our coverage to those whom we believe are the principal prescribers of our medications. We anticipate that more precise product detailing rather than broad physician coverage will enable our sales team to be more productive overall and to more effectively communicate with those prescribers who are most receptive to our product promotion and education. We believe that this realignment will serve us well as we look for opportunities to expand our sales force capacity in 2008. We expect to add at least 200 sales professionals during the course of the year to support and accommodate the OMNARIS AQ and ALVESCO HFA products, which we plan to launch in 2008. It is our belief that this realignment and controlled sales force expansion will be key components in driving future prescription and market share growth for our products and in successfully launching our two newest products.

### LUNESTA®

In 2007, LUNESTA, our insomnia treatment sold in the U.S., achieved total revenues of \$600.9 million for the year, which was a 6.3 percent increase over 2006. Approximately 10 percent of adults in the U.S. suffer from insomnia symptoms that include trouble falling asleep and/or difficulty staying asleep, with an impact on next-day functioning. During 2007, which was the





Commercial



product's second full year on the market, nearly seven million prescriptions were written for patients with both transient and chronic insomnia. Of those, more than three million were prescription refills, which we believe is an indicator of patient loyalty and satisfaction with the product.

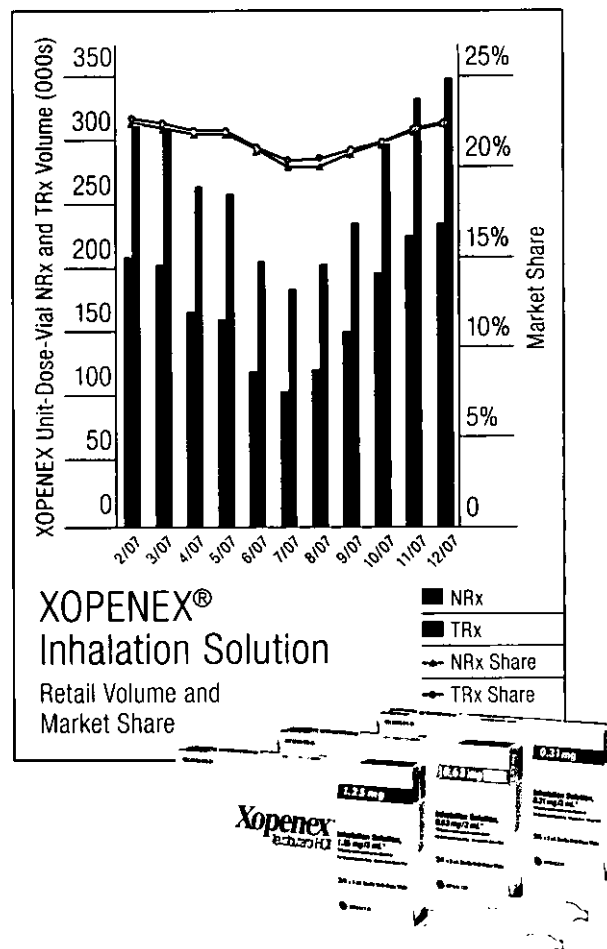
Sedative hypnotics continue to be a competitive therapeutic area, and in 2007 we saw the first generic entrant with the introduction of generic zolpidem. As with any therapeutic category into which a generic competitor is launched, branded sedative hypnotics saw some decline in market share. While we recognize that inexpensive generics may initially appeal to prescribers, managed care plans and even patients, we believe that a combination of factors will help to drive LUNESTA prescription growth in the coming year.

At the close of 2007, LUNESTA demonstrated increasing commercial success in managed care access versus other products, including AMBIEN CR® (zolpidem tartrate extended release). As of December 2007, LUNESTA access was unrestricted, or not subject to prior authorization, for approximately 90 percent of managed care lives, which was an improvement from approximately 80 percent for LUNESTA in December 2006 and more than ten percentage points higher than AMBIEN CR access in December 2007. We believe that continued strength in managed care access is a significant advantage for LUNESTA.

After extensive review, we also identified several strategic imperatives designed to grow LUNESTA market share in 2008. These strategic imperatives include further amplifying the core LUNESTA selling messages, effectively targeting key physician segments for various promotional initiatives, leveraging our enhanced formulary status with major managed care organizations and re-energizing our physician-oriented and direct-to-consumer promotional campaigns.

#### XOPENEX® INHALATION SOLUTION

XOPENEX Inhalation Solution is our short-acting beta-agonist product indicated for the treatment or prevention of bronchospasm in patients six years of age and older with reversible obstructive



airway disease, such as asthma and chronic obstructive pulmonary disease (COPD). Commercially available since 1999, XOPENEX Inhalation Solution has become a mainstay in the treatment of acute episodes of bronchoconstriction.

In the Medicare marketplace, the past year was a challenging one for our XOPENEX Inhalation Solution product. In May, the Centers for Medicare and Medicaid Services (CMS) announced that it would discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and bundle the Medicare Part B payment amount for this product with generic albuterol inhalation solution products. The revised payment structure resulted in a reimbursement rate for XOPENEX Inhalation Solution that was significantly lower than the reimbursement rate that had previously been granted our product under Medicare Part B. This new rate

was implemented in July 2007 and resulted in reduced overall revenues from the Medicare Part B channel for our XOPENEX Inhalation Solution product for the year. Until recently, it had been estimated that approximately 25 to 30 percent of XOPENEX Inhalation Solution units were subject to reimbursement under Medicare Part B and 70 to 75 percent were dispensed through retail, hospital and other channels.

We expect that a reduced reimbursement rate for XOPENEX Inhalation Solution under Medicare Part B will remain in place in the future. However, by actively contracting with a number of home health care companies after the CMS decision to reduce the reimbursement rate for XOPENEX Inhalation Solution, we were successful in helping to maintain availability of XOPENEX Inhalation Solution for Medicare Part B beneficiaries.

At the end of 2007, legislation was signed into law, the effect of which will enable XOPENEX Inhalation Solution to continue to be reimbursed at a blended XOPENEX Inhalation Solution/generic

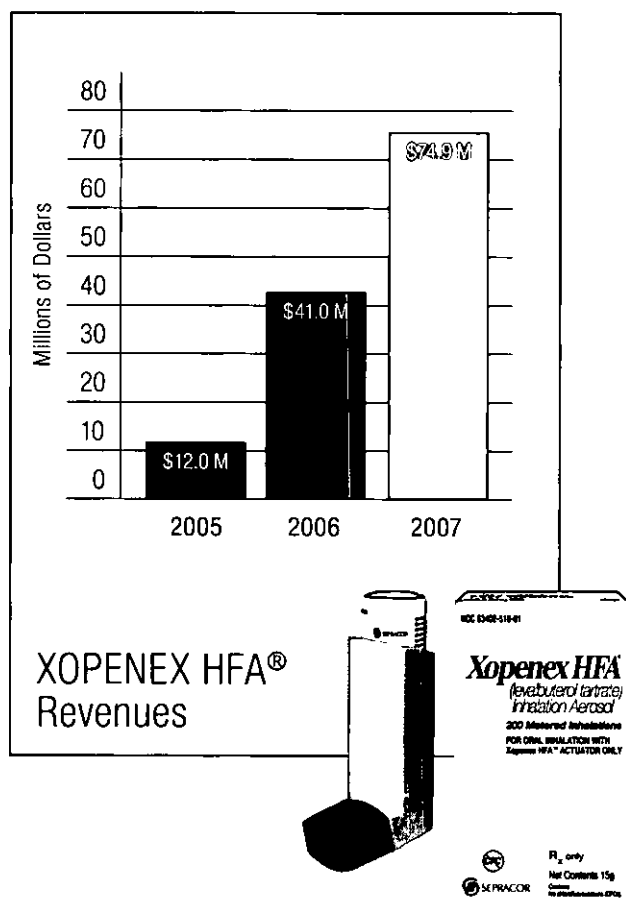
albuterol average selling price rate while generic albuterol will be reimbursed at its own weighted average selling price. This legislation went into effect on April 1, 2008, and we believe it may reduce the potential for inappropriate reimbursement incentives influencing providers' dispensing decisions related to short-acting beta-agonist therapies.

#### XOPENEX HFA®

XOPENEX HFA is our handheld, HFA-propelled MDI formulation of levalbuterol. Indicated for the treatment or prevention of bronchospasm in patients four years of age and older with reversible obstructive airway disease such as asthma or COPD, XOPENEX HFA provides patients with a convenient, portable means of administering their medication, wherever and whenever they need it.

In late 2006, a transition began among short-acting beta-agonist MDIs. The Montreal Protocol on Substances that Deplete the Ozone Layer is an international agreement that requires the phase-out of substances that deplete the ozone layer. In compliance with this international agreement, the FDA mandated that all albuterol-containing products containing chlorofluorocarbons (CFCs) must be phased-out and no longer produced after December 31, 2008. The changeover that began in late 2006 continued in 2007 with accelerated transition of patients from generic CFC albuterol inhalers to branded HFA inhalers. At the end of 2007, approximately 40 percent of short-acting beta-agonist MDIs in the marketplace were still CFC-based.

While this transition period represents an opportunity for patients to gain access to XOPENEX HFA, we also continue to believe that there is a strong rationale for more patients already taking XOPENEX Inhalation Solution to begin using XOPENEX HFA as their short-acting beta-agonist MDI. A significant number of prescriptions written for XOPENEX Inhalation Solution are for pediatric patients who may not have the dexterity to use a handheld inhaler. As these patients mature, however, their dexterity and their needs for a portable means of administering their medication change. For patients who have grown up with



XOPENEX Inhalation Solution, transitioning to XOPENEX HFA as an adolescent or adult should be a natural progression. By raising awareness of the availability of XOPENEX HFA to physicians and caregivers of those patients currently using the nebulized form, we believe that we will be able to expand XOPENEX HFA utilization in the years to come.

## BROVANA®

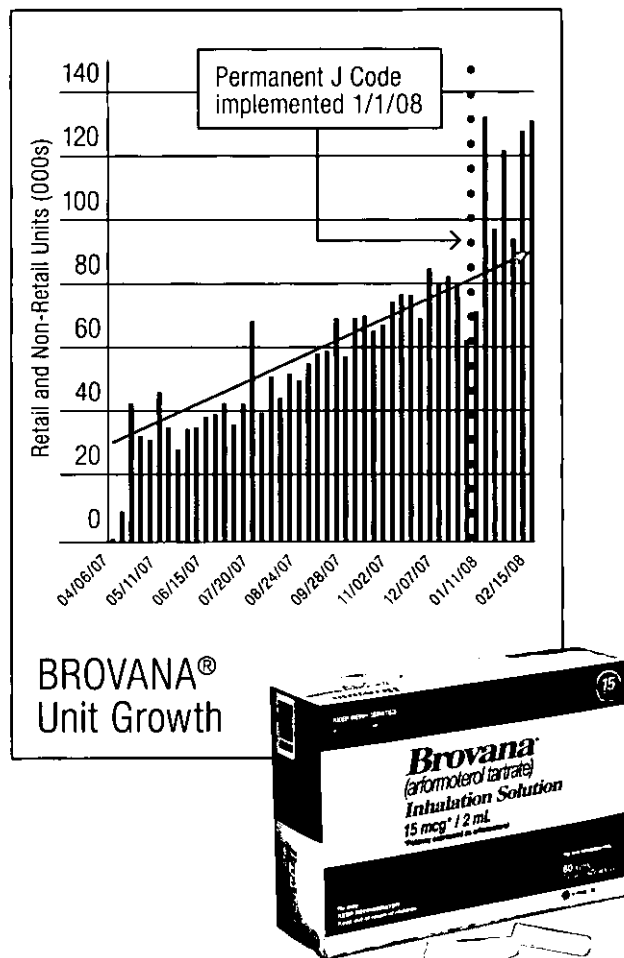
BROVANA was launched in April 2007 as a twice-daily maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. According to the National Heart Lung and Blood Institute, an estimated 24 million people in the U.S. suffer from COPD, but only 12 million have been diagnosed.

Patients with COPD are typically older adults who have had a long history of cigarette smoking. The majority of patients afflicted with COPD are also Medicare beneficiaries. In November 2007, CMS established a permanent and unique reimbursement code, or J code, for BROVANA under Medicare Part B. Effective on January 1, 2008, this permanent J code for our product should enable easier and more timely reimbursement to home health care providers whose patients are prescribed and dispensed BROVANA for maintenance treatment of their COPD symptoms. We anticipate that the implementation of this J code will ultimately provide patients with easier access to the medication that they require.

In 2007, we saw steady growth from our BROVANA product, and we exited the year with our highest monthly unit volume of more than 400,000 units sold through both retail and non-retail channels in December. Since the January 1, 2008 implementation of our permanent J code, we have seen a step-change increase in units sold. We believe we will see increased growth in BROVANA units during 2008 due in large part to what we anticipate will be continued growth in the non-retail sector, specifically among Medicare Part B beneficiaries.

## OMNARIS™ AQ

In January 2008, we acquired U.S. commercialization rights to OMNARIS AQ from Nycomed. An inhaled nasal corticosteroid, OMNARIS AQ is indicated for the treatment of nasal symptoms



associated with seasonal allergic rhinitis in adults and children 6 years of age and older, and for perennial allergic rhinitis in adults and adolescents 12 years of age and older. OMNARIS AQ is currently the only corticosteroid nasal spray designed as a site-activated prodrug and formulated in a hypotonic solution, which may help to promote adherence and absorption of the medication in the nasal passages. Intranasal corticosteroids are well-accepted as first-line therapy for the treatment of allergic rhinitis, and they work by reducing inflammation – the major underlying cause of the clinical symptoms of allergic rhinitis.

Included in Nycomed's NDA were the results from 11 clinical trials of OMNARIS AQ involving more than 2,100 patients. In a 52-week study, OMNARIS AQ demonstrated sustained improvements in key nasal symptom scores without evidence of loss of effect when



used daily over the year-long treatment period – an attribute that we believe may encourage patient compliance.

We believe that OMNARIS AQ is a strategically seamless fit with our proprietary portfolio of respiratory products. Our sales and marketing organization has had significant experience in promoting XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA to respiratory specialists and primary care

physicians in the U.S., and we believe that this experience, combined with well-established relationships with hospitals and respiratory specialists, increased sales capacity, wide sampling and trade distribution, competitive managed care access and anticipated direct-to-consumer marketing, provide a strong platform from which to launch our newest product. We expect to begin commercializing OMNARIS AQ in April 2008.

Allergic rhinitis is a chronic inflammatory disease of the nasal mucosa causing sneezing, itching, nasal congestion and discharge. Seasonal allergic rhinitis is caused by substances that trigger allergies and is sometimes referred to as "hay fever." Perennial allergic rhinitis is a chronic condition caused by various irritants, also known as triggers, such as pet dander and dust. Poorly controlled allergies can result in impairments in day-to-day activities as well as a reduction in a patient's quality of life. According to the American Academy of Allergy, Asthma, and Immunology, more than 40 million Americans are currently estimated to suffer with allergic diseases, and allergic diseases are the sixth leading cause of chronic disease in the U.S.

#### ALVESCO® HFA

As part of our agreement with Nycomed, we also secured the rights to commercialize ALVESCO HFA in the U.S. Approved by the FDA in January 2008, ALVESCO HFA is a corticosteroid

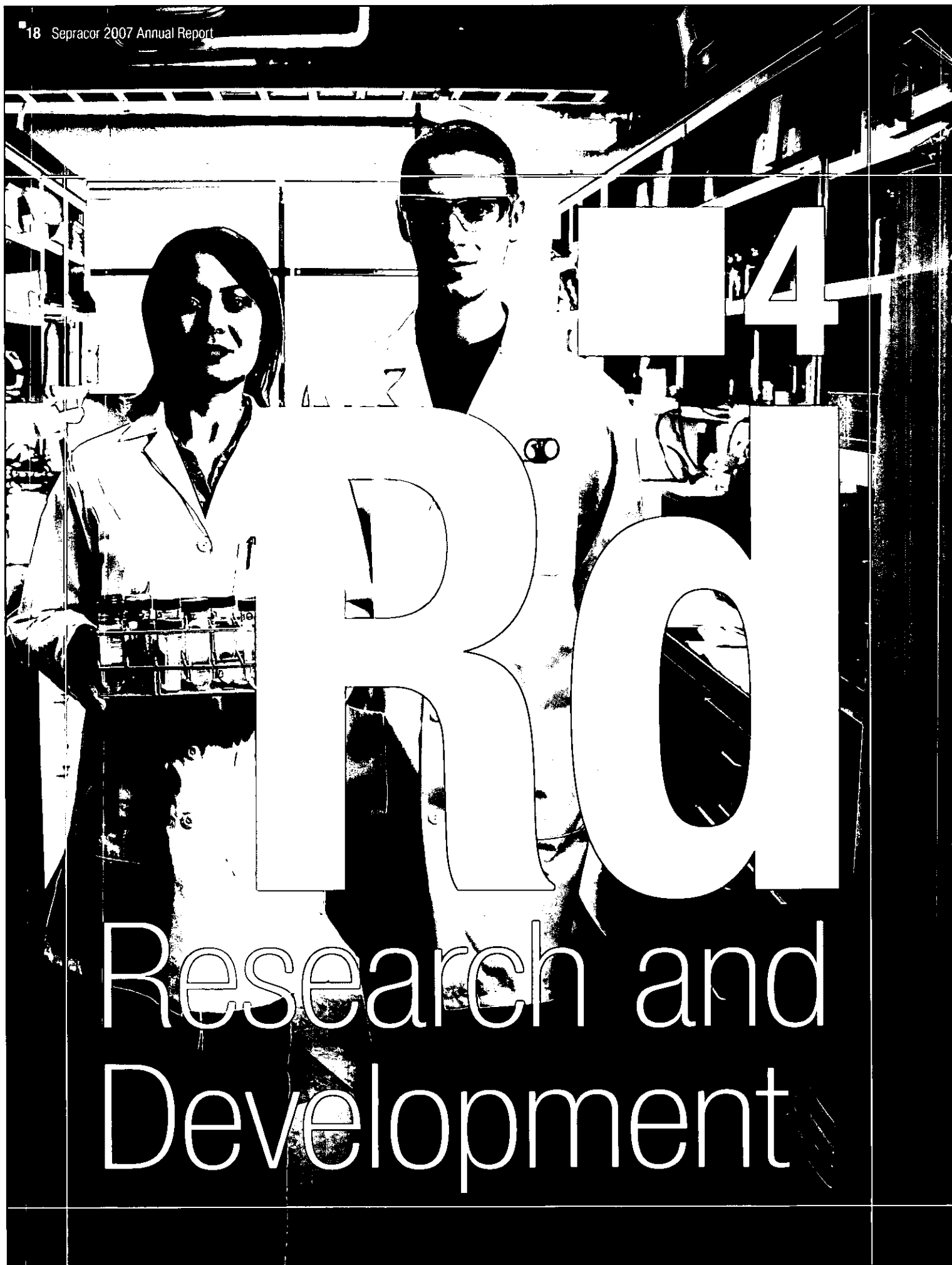
delivered by an HFA MDI and is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 12 years of age and older.

ALVESCO HFA, which we expect to be commercially introduced during the second half of 2008, complements our respiratory franchise, particularly our XOPENEX brand product line. Adding ALVESCO HFA to our product portfolio will enable us to offer health care professionals complementary medications to prescribe to their patients with asthma; our XOPENEX line of products can provide patients with relief from bronchospasm, and ALVESCO HFA can benefit patients as a first-line, maintenance therapy that can be used prophylactically to control airway inflammation.

Nycomed's NDA for ALVESCO HFA included data from five double-blind, placebo-controlled clinical trials of 720 patients aged 12 years of age and older with mild to severe persistent asthma. ALVESCO HFA has been approved in more than 40 countries worldwide and has been commercially introduced in at least 30 countries, with additional launches expected in 2008.

Asthma is a chronic, inflammatory condition that is caused by increased reaction in the airways to various triggers. Asthma may be life-threatening to people experiencing an acute exacerbation. According to the Centers for Disease Control and Prevention, in 2005, more than 22 million people in the U.S. had asthma, 12.2 million of whom had experienced an asthma attack during the previous year.

We believe that the changes we have put in place during the past year have served to better align our commercial organization to optimize our assets and position ourselves for stronger growth from our established products and our planned product launches in 2008. We believe that today we have a stronger commercial organization with higher productivity potential on a sustainable basis.



# R&D

## Research and Development

## The Innovation Element

# Delivering tomorrow's medicines starts with our ability to recognize opportunities today.

Advancement of our clinical and preclinical pipeline of pharmaceutical candidates is a key strategic focus of our organization. Sepracor's research and development infrastructure has the capacity to advance pharmaceutical candidates from any stage of development, from preclinical to clinical trials, and through the FDA review process. Our highly scalable drug development organization is comprised of approximately 230 internal personnel responsible for our critical value drivers with oversight of more than 1,000 additional contract research personnel available around the world to execute our research and development initiatives. Using both internal and external

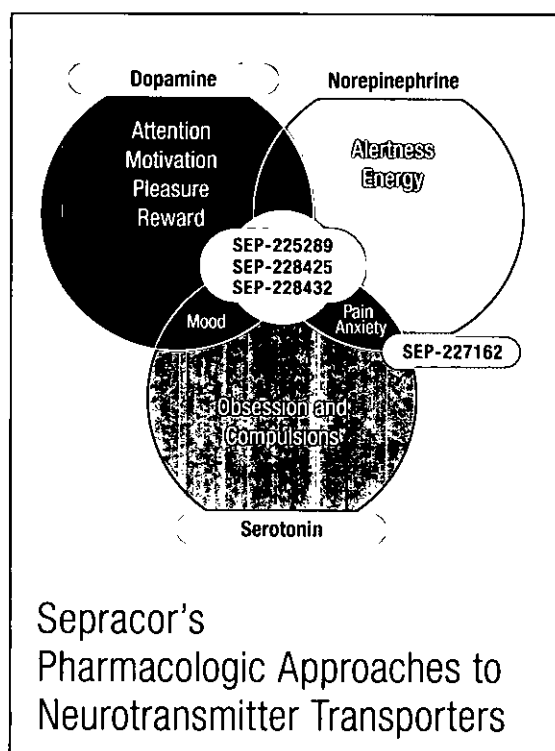
resources, we have expanded our scope internationally, managing and executing clinical trials overseas and successfully working with the FDA's regulatory counterparts in the EU and Japan.

The focus of our research and discovery effort has been principally in the development of compounds that address respiratory and CNS disorders. Our current pharmaceutical pipeline includes a number of candidates that we advanced in 2007 for the treatment of depression, as well as for generalized anxiety disorder and cognition. In early 2008, we further broadened and deepened our pharmaceutical pipeline with the acquisition of rights to three candidates from Nycomed, which are targeted for treatment of respiratory disorders, and a new anti-epileptic compound from Bial, for which Phase III studies have been completed.

### COMMERCIALIZED PRODUCTS

Research and clinical development do not cease on approval and commercialization of a product. In 2007, we devoted significant resources to further study our marketed products, both as part of Phase IV commitments to the FDA and as part of our overall strategy to fully leverage our product franchises.

Our eszopiclone product franchise (known as the LUNESTA brand in the U.S.) made significant advances in 2007 by expanding into international markets. In addition to successfully partnering with Eisai and GSK for worldwide commercialization, Sepracor submitted a Marketing Authorization Application, or MAA, for eszopiclone to the EU regulatory authorities during the second



half of 2007. Comprised of data from all of our completed preclinical and clinical studies of LUNESTA at that time, the MAA included results from 122 preclinical and 35 clinical studies. These studies evaluated more than 5,500 adult and older adult (>65 years of age) subjects, including patients with transient or chronic insomnia. In addition to studies of LUNESTA in patients with insomnia and co-existing conditions, two six-month, placebo-controlled studies in primary insomnia, as well as two driving studies, were included in the submission. The MAA remains under European regulatory review, and we are targeting approval of the product in the EU for the end of 2008.

During the year, we also initiated a large-scale, European, six-month study of eszopiclone co-administered with the antidepressant, venlafaxine, in subjects with insomnia and co-existing major depressive disorder. This ongoing, large-scale trial seeks to assess the potential benefit of eszopiclone in reduction of symptoms of depression and in relapse prevention.

## CENTRAL NERVOUS SYSTEM RESEARCH AND DEVELOPMENT

### Epilepsy

With the successful in-licensing of Bial's anti-epileptic compound at the end of 2007, we expect to devote significant resources to preparing the SEP-0002093 (eslicarbazepine acetate) NDA for submission to the FDA. This NDA will include results from three Phase III studies that were conducted in 22 countries and more than 1,000 patients. In these studies, patients were randomized to acute double-blind therapy for 18 weeks followed by a one-year, open-label extension. SEP-0002093 is designed for once-daily administration and to offer additional seizure control, simpler dosage titration and improved quality of life to patients with partial epilepsy.

According to the National Institute of Neurological Disorders and Stroke, epilepsy is a brain disorder in which neurons in the brain signal abnormally causing strange sensations, emotions and behavior, or sometimes convulsions, muscle spasms and loss of consciousness. More than two million people in the U.S. have been diagnosed with epilepsy or have experienced a seizure.

SEPRACOR		CNS PRODUCTS AND PIPELINE					
PRODUCT	INDICATION	Preclinical	Phase I	Phase II	Phase III/ NDA Prep	FDA Approved	Launched
LUNESTA®	Insomnia						
CANDIDATE	TARGET INDICATION	Preclinical	Phase I	Phase II	Phase III/ NDA Prep	FDA Approved	Launched
SEP-0002093*	Epilepsy						
SEP-225289	Depression						
SEP-225441	Anxiety						
SEP-227162	Depression						
SEP-228425	Depression/Pain						
SEP-228432	Depression						
SEP-227900	Neuropathic Pain						
MECHANISM	TARGET INDICATION	Preclinical	Phase I	Phase II	Phase III/ NDA Prep	FDA Approved	Launched
Serotonin, Norepinephrine Dopamine Reuptake Inhibitors	Depression						
DAAO Inhibitors	Schizophrenia						
Alpha <sub>2,3</sub> GABA <sub>A</sub> Agonist	Anxiety/Panic						

\* BIA 2-093 under license from Bial

We expect to submit our NDA for SEP-0002093 at the end of 2008 or in early 2009 with the potential for product launch in late 2009 or in early 2010.

## Depression

Our most advanced clinical candidate for the treatment of depression, SEP-225289, moved into a Phase II, 400-patient study during 2007. Referred to as a triple reuptake inhibitor, SEP-225289 has demonstrated in preclinical trials, a high binding affinity to the three neurotransmitter transporters that are associated with modulating depression – serotonin, norepinephrine and dopamine. It is believed that a balanced action across each of these three neurotransmitter transporters has the potential to offer better outcomes in the treatment of depression.

We believe that we are among the scientific leaders in triple reuptake inhibitor research. In 2007, we filed IND applications for two additional triple reuptake inhibitors for the treatment of depression, SEP-228425 and SEP-228432. These early Phase I candidates have been shown in preclinical trials to have different binding ratios on each of the three neurotransmitter transporters compared to SEP-225289, potentially offering utility in treating conditions beyond depression, including pain and cognition.

SEP-227162 rounds out our current portfolio of pharmaceutical candidates for the treatment of depression. Unlike our triple reuptake inhibitors, SEP-227162 has demonstrated balanced binding to two of the three neurotransmitter transporters: serotonin and norepinephrine. We anticipate advancing SEP-227162 to Phase II/III during 2008.

According to the National Institute of Mental Health, depressive disorders affect nearly 21 million adults in the U.S. in any given year, and according to the World Health Organization, depression is the leading cause of disability among both men and women worldwide.



According to the National Institute of Mental Health, when viewed using brain-imaging technology, such as magnetic resonance imaging (MRI), the parts of the human brain that are responsible for regulating mood, thinking, sleep, appetite and behavior appear to function abnormally in people who are depressed as compared to those who are not depressed, and neurotransmitters – the chemicals that allow brain cells to communicate – appear to be out of balance.

## Anxiety

Another area of interest for us is in developing a new treatment for anxiety. SEP-225441 is a compound that works as an agonist of the alpha receptor of the gamma aminobutyric acid, or GABA, complex. We believe that effectively and precisely modulating the response of alpha receptors in the GABA complex has the potential to decrease anxiety without sedation commonly associated with GABA<sub>A</sub> agonists. We are also evaluating SEP-225441 as a potential treatment for panic disorder. In 2007, SEP-225441 advanced into one of three planned Phase II studies. This key initial Phase II study is expected to enroll approximately 400 patients.



Anxiety disorders include panic disorder, obsessive-compulsive disorder, post-traumatic stress disorder, generalized anxiety disorder and phobias. According to the National Institute of Mental Health, approximately 40 million adults in the U.S. have an anxiety disorder in a given year.

## RESPIRATORY RESEARCH AND DEVELOPMENT

### Allergic Rhinitis

In January 2008, we successfully obtained three development candidates from Nycomed, one of which is being studied for the treatment of allergic rhinitis. This candidate, which is comprised of the prodrug, ciclesonide, and formulated in an HFA MDI for nasal application, is currently in Phase II clinical development. This Phase II candidate is being considered as a line extension to OMNARIS AQ, a nasal corticosteroid that we expect to commercially introduce in 2008. There are currently no treatments for allergic rhinitis commercially available in an HFA MDI formulation, and we

believe that OMNARIS HFA has the potential to be a highly differentiated treatment for allergic rhinitis. We expect to initiate Phase III studies in 2008.

### Asthma

Our agreement with Nycomed also provides us with additional candidates for the treatment of asthma, a therapeutic area in which we have a great deal of experience, both in development and commercial application. One of our new candidates is a combination therapy that is comprised of ciclesonide and a long-acting beta-agonist. It is believed that this early clinical candidate would combine the anti-inflammatory properties of an inhaled corticosteroid with the long-acting, bronchodilatory benefits of a beta-agonist, in one medication.

We are also pursuing development of an inhalation solution line-extension formulation of ciclesonide, which would complement our XOPENEX brand product franchise. This candidate, which is in preclinical development, is targeted for the treatment of asthma.

SEPRACOR		RESPIRATORY PRODUCTS AND PIPELINE					
PRODUCT	INDICATION	Preclinical	Phase I	Phase II	Phase III/ NDA Prep	FDA Approved	Launched
XOPENEX® Inhalation Solution	Asthma/COPD						
XOPENEX HFA®	Asthma/COPD						
BROVANA®	COPD						
OMNARIS™ (ciclesonide)†	Allergic Rhinitis						
ALVESCO® (ciclesonide)‡	Asthma						
CANDIDATE	TARGET INDICATION	Preclinical	Phase I	Phase II	Phase III/ NDA Prep	FDA Approved	Launched
OMNARIS™ HFA MDI	Allergic Rhinitis						
Ciclesonide + LABA* Combo.	Asthma						
Ciclesonide Inhalation Solution	Asthma						
MECHANISM	TARGET INDICATION	Preclinical	Phase I	Phase II	Phase III/ NDA Prep	FDA Approved	Launched
Long-Acting Beta-Agonists	Asthma/COPD						

† Target launch 1H '08

‡ Target launch 2H '08

\* Long-acting beta-agonist

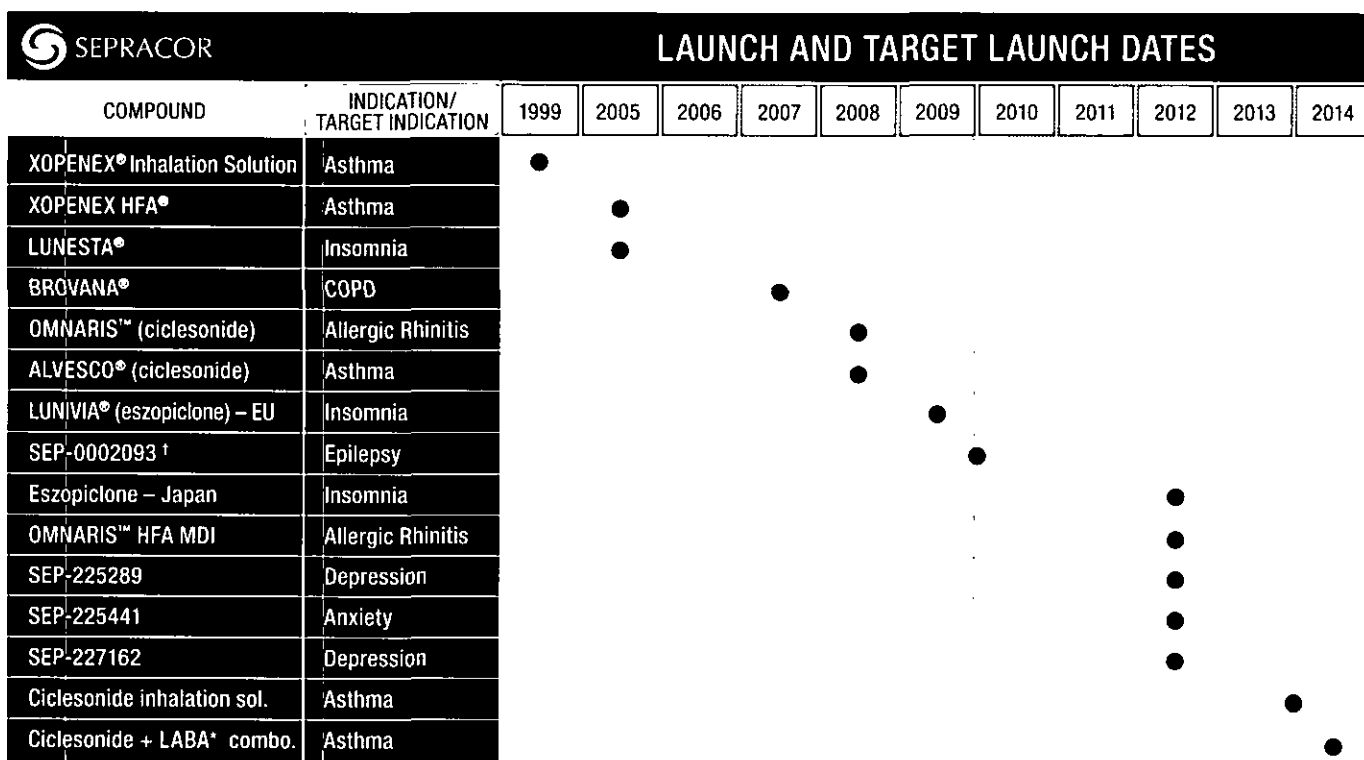
## DISCOVERY PRODUCTIVITY

In 2007, Sepracor accelerated its transition from its foundation in drug development based on chiral chemistry to identifying and advancing new chemical entities generated by our discovery research organization. Our current discovery focus is to identify new leads for depression, schizophrenia, anxiety, pain, cognition, sleep/wake and asthma.

Our internal discovery capabilities are augmented by strategic partnerships with PsychoGenics and Scottish Biomedical, among others, and by outsourcing partnerships for *in vitro* and *in vivo* compound testing. In order to seize evolving opportunities in discovery research and achieve effective cost controls, in 2007 we re-energized our discovery commitments globally. During the year, we partnered for biology research in the U.S., the EU, Asia and Australia, supported experimental medicine efforts in Europe and the U.S., and contracted for scale-up process chemistry in India and synthetic chemistry in China. We believe that these external

investments complement our internal capabilities, enhance our productivity and result in a flexible model for discovery research in the 21st century.

During the past four years, we have succeeded in obtaining FDA approvals of three NDAs, five INDs were filed, and in the last year, six early candidates advanced in development and new chemical entities were introduced to our pipeline – all of which reflect our research and development organization's capability and high productivity. With our current pipeline of pharmaceutical candidates, we have the potential to launch an additional seven new products between 2009 and 2014 in addition to the two planned product launches in 2008. Our research and development efforts are our growth engine of the future. As we broaden and deepen our pipeline, continue to make progress with our clinical and preclinical candidates, advance our new partnered opportunities and expand our reach worldwide, we believe we will strengthen and solidify our growth position well into the future and, in essence, improve health through innovation.



† BIA 2-093 under license from Bial

\* LABA = long-acting beta-agonist

Sepracor's estimations of target launches assume a 10-month regulatory review cycle.

## The Human Element

# Harnessing the passion of our people to make a world of difference.

We believe that our success is directly attributable to our people. Each employee, either directly or indirectly, is involved in the discovery, development and commercialization of the medications that make patients' lives better.

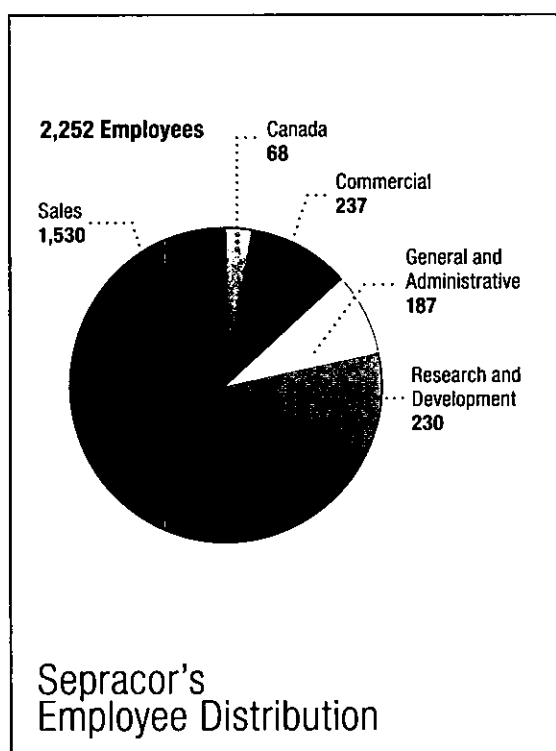
There are specific core values that our employees strive to incorporate into their daily work lives. Our six core values express the importance of our customers, our people, innovation, integrity and professionalism, peak performance and accountability at Sepracor. These core values have differentiated our culture historically and reflect the fundamental and deeply held beliefs that shape our culture and guide our behavior.

As an organization, our core values form the basis from which to achieve our objectives of delivering enhanced performance and productivity across our organization, fully leveraging our product franchises, growing our research and development pipeline and aggressively pursuing corporate development and licensing opportunities. Accomplishing each of these objectives is reliant on building and capitalizing on the strengths of our individual employees and rewarding them for their achievements. We believe in nurturing the talents that our employees bring to the organization and are working to establish a succession plan for key functions within the company, creating an environment that benefits both high-potential employees and our business.

These core values are also embodied in Sepracor's Code of Conduct and Ethics and in our unwavering commitment to build and strengthen a vision-based, people-centric culture that ensures that all of our plans and activities are carried out with the highest standards of compliance, ethics and integrity.

We believe that employee recognition, talent development, competitive compensation and an environment that urges a balance between personal priorities and workplace productivity have helped to keep our employee turnover rates among the lowest in the industry. We have a diverse and highly educated workforce that has benefited from significant experience within the pharmaceutical industry, and all of these attributes have helped to establish our company's reputation as a premier specialty pharmaceutical company.

Our dedication to the betterment of human life is a cornerstone of what makes us Sepracor. We are proud of our accomplishments and look forward to surpassing them in the months and years to come.



5

PE

People



SEPRACOR

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Financial

2007 Form 10-K

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Cd

Corporate  
Development

3

Cm

Commercial

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Rd

Research and  
Development

5

Pe

People

# SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

## FORM 10-K

FOR ANNUAL AND TRANSITION REPORTS PURSUANT  
TO SECTIONS 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

(Mark One)



ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2007

OR



TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE  
SECURITIES EXCHANGE ACT OF 1934

For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-19410

**Sepracor Inc.**

(Exact Name of Registrant as Specified in its Charter)

Delaware

(State or Other Jurisdiction of  
Incorporation or Organization)

22-2536587

(IRS Employer Identification No.)

84 Waterford Drive,

Marlborough, Massachusetts

(Address of Principal Executive Offices)

01752

(Zip Code)

Registrant's telephone number, including area code: (508) 481-6700

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, \$.10 par value

(Title of class)

Nasdaq Global Select Market

(Name of Exchange on which Registered)

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to the Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer or smaller reporting company. See the definitions of "large accelerated filer", "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☒

Accelerated filer ☐

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting common stock held by nonaffiliates of the registrant based, on the last reported sale price of the common stock on the Nasdaq Global Select Market on June 30, 2007, was approximately \$4,398,899,000.

The number of shares outstanding of the registrant's class of common stock as of February 15, 2008 was 112,030,558 shares.

### DOCUMENTS INCORPORATED BY REFERENCE

Proxy Statement for the 2008 Annual Meeting of Stockholders—Part III

**Sepracor Inc.**  
**FORM 10-K**

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## **Explanatory Note**

### **Restatement of Prior Period Financial Information**

This Annual Report on Form 10-K includes the restatement of our consolidated financial statements as of and for the years ended December 31, 2006 and 2005. This report also includes the restatement of the selected financial data as of and for the years ended December 31, 2006, 2005, 2004 and 2003.

As announced in our Current Report on Form 8-K, which we filed with the Securities and Exchange Commission, or SEC, on January 28, 2008, we concluded that our previously filed financial statements should no longer be relied upon due to matters relating to our government pricing discussed in this Explanatory Note, Note U "Restatement of Financial Statements Based on Review of Government Pricing" to our consolidated financial statements included in this report and elsewhere in this Form 10-K.

Revenue is recognized for amounts that are fixed or determinable assuming all other applicable criteria are met. We recently determined that Public Health Service, or PHS, discounts were provided to non-PHS covered entities. This circumstance creates uncertainty as to whether a new best price was set in prior periods. If a new best price was set, additional Medicaid rebates will be required to be paid. A portion of the revenue we previously recognized is therefore contingent on the outcome of this matter. Revenue has been reduced and rebate liabilities increased to adjust for the amounts previously invoiced and received that are contingent and do not qualify for revenue recognition. The restatement for such contingent amounts reflects our best estimate of the net revenue that should have been recognized in the respective periods.

Under the Medicaid rebate program, we are obligated to pay a rebate to each participating State Medicaid program for each unit of product reimbursed by Medicaid. The amount of the rebate is set by law as the greater of (a) 15.1% of the average manufacturer price, which is referred to as AMP, or (b) the difference between AMP and the Medicaid best price, which is the lowest price available from us to any customer not excluded by law from that determination. The determination of whether a new best price was set is uncertain and is a matter of judgment that will be subject to disclosure to the Centers for Medicare and Medicaid Services, or CMS. A determination of the actual amount of payments required may change as a result of future interactions with CMS and we cannot be certain that we will not be subject to fines, penalties and interest.

We also excluded transactions involving the Pennsylvania General Assistance Program, or PAGA, from our calculation of the Medicaid best price based on the belief that PAGA, a State Pharmaceutical Assistance Program, was excluded from Medicaid best price. Despite review of available materials, we cannot be sure that PAGA is excluded from Medicaid best price. While we may have incorrectly excluded the PAGA transactions, we do not believe including the transactions would have set the Medicaid best price for any period in which the PHS price was given to an entity that was not a PHS covered entity, where the PHS price was lower than the PAGA price and the PHS price is determined to be included in best price. We notified CMS of these possible PHS and PAGA errors in January 2008.

As a result of these matters, our management, with the oversight of our Audit Committee, is reviewing our government pricing activities affected by the material weakness described below. The aggregate amount by which we have reduced revenue in prior periods is approximately \$60.2 million. The amount by which we have reduced revenues for the first three quarters of 2007, combined, and the fiscal years ended December 31, 2006 and 2005 is approximately \$8.2 million, \$13.4 million and \$19.8 million, respectively. The amount by which we have reduced revenues for the fiscal years ended December 31, 2004 and 2003 is approximately \$7.8 million and \$8.0 million, respectively. Included in our accumulated deficit balance at January 1, 2003 is the cumulative impact of a \$3.0 million reduction of revenue for periods prior to the year ended December 31, 2003.

The amounts by which we have reduced revenues for contingent rebates were based on management's best estimates and assumptions made prior to any concurrence by CMS. These amounts



may change as a result of future interactions with CMS and we cannot be certain that we have not overestimated the amount of additional rebates we may be required to pay, that the amount of any additional rebate payments or other payments we may owe will not exceed our current estimates, or that we will not be subject to fines, penalties or interest. The restatement and its impact on fiscal years ended December 31, 2006 and 2005 are discussed in more detail in Note U to our consolidated financial statements, which are included herein.

While we have restated the unaudited quarterly information in Note T in our consolidated financial statements and intend to amend and restate our quarterly reports on Form 10-Q for the fiscal quarters ended March 31, June 30 and September 30, 2007 and 2006, we have not amended and do not intend to amend any of our other previously filed reports for the periods affected by the restatement. As we have previously announced, the consolidated financial statements and related information contained in such previously filed reports should no longer be relied upon.

#### **Identification of Material Weakness**

In connection with the restatement of our Medicaid rebate reserve, we identified a material weakness in our disclosure controls and procedures and internal controls over financial reporting as of December 31, 2007 and reported those to our Audit Committee. The material weakness, which is further described below in Item 9A of this Form 10-K resulted in the restatement of our prior period financial information included in this report.

### **Cautionary Statement Regarding Forward-Looking Statements**

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 concerning our business, operations and financial condition, including statements with respect to the safety, efficacy and potential benefits of our products and products under development, expectations with respect to the timing and success of the development and commercialization of our products and product candidates and acquisitions of technologies, product candidates, approved products and/or businesses, the timing and success of the submission, acceptance and approval of regulatory filings, the scope of patent protection with respect to our products and product candidates, our review of government pricing and the related restatement of certain historical financial statements and information with respect to the other plans and strategies for our business and the business of our subsidiaries. All statements other than statements of historical facts included in this report regarding our strategy, future operations, timetables for product testing, development, regulatory approvals and commercialization, acquisitions, financial position, costs, prospects, plans and objectives of management are forward-looking statements. When used in this report the words “expect,” “anticipate,” “intend,” “plan,” “believe,” “seek,” “will,” “estimate,” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. Because these forward-looking statements involve risks and uncertainties, actual results could differ materially from those expressed or implied by these forward-looking statements for a number of important reasons, including those discussed under “Risk Factors”, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report.

You should read these forward-looking statements carefully because they discuss our expectations about our future performance, contain projections of our future operating results or our future financial condition, or state other “forward-looking” information. You should be aware that the occurrence of any of the events described under “Risk Factors” and elsewhere in this report could substantially harm our business, results of operations and financial condition and that upon the occurrence of any of these events, the trading price of our common stock could decline.

We cannot guarantee any future results, levels of activity, performance or achievements. The forward-looking statements contained in this annual report on Form 10-K represent our expectations as of the date of this annual report on Form 10-K and should not be relied upon as representing our expectations as of any other date. Subsequent events and developments will cause our expectations to change. However, while we may elect to update these forward-looking statements, we specifically disclaim any obligation to do so, even if our expectations change.

## **PART I**

### **Item 1. Business.**

#### **The Company**

We are a research-based pharmaceutical company focused on discovering, developing and commercializing differentiated products that address large and growing markets and unmet medical needs and that are prescribed principally by primary care physicians and certain specialists. Our proprietary compounds are either:

- Single isomers or active metabolites of existing drugs, or
- New chemical entities that are unrelated to marketed drugs.

Our drug research and development program, together with our corporate development and licensing activities, have yielded a portfolio of drugs and drug candidates intended to treat a broad

range of indications. We are currently concentrating our product development efforts in two therapeutic areas: respiratory diseases and central nervous system, or CNS, disorders.

In our isomer and metabolite development program, we identify existing drugs that might, in single-isomer or active-metabolite forms, provide significant advances over existing therapies within the indications of the parent compound or in new indications. We then develop isomers or metabolites designed to offer benefits over both the parent drugs and competitive compounds, such as reduced side effects, improved therapeutic efficacy, effectiveness for new indications or improved dosage forms.

Our development program for new chemical entities encompasses a more traditional approach to drug development. In this program, we are seeking to discover novel compounds unrelated to existing commercial compounds that have the potential to provide benefits over existing treatments or provide new therapies for diseases currently lacking effective treatment.

Our currently marketed products are:

- XOPENEX® (levalbuterol HCl) Inhalation Solution, a short-acting bronchodilator, for the treatment or prevention of bronchospasm in patients six years of age and older with reversible obstructive airway disease;
- XOPENEX HFA® (levalbuterol tartrate) Inhalation Aerosol, a hydrofluoroalkane, or HFA, metered-dose inhaler, or MDI, for the treatment or prevention of bronchospasm in adults, adolescents and children four years of age and older with reversible obstructive airway disease;
- BROVANA® (arformoterol tartrate) Inhalation Solution, a long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease, or COPD, including chronic bronchitis and emphysema; and
- LUNESTA® (eszopiclone) for the treatment of insomnia in adults.

We market these products in the United States to primary care physicians, allergists, pulmonologists, pediatricians, hospitals, psychiatrists and sleep specialists, as appropriate, primarily through our sales organization comprising approximately 1,600 sales professionals. In addition, we recently obtained from Nycomed GmbH, or Nycomed, the exclusive U.S. distribution rights to two products that have been approved by the United States Food and Drug Administration, or FDA, OMNARIS™ AQ (ciclesonide) nasal spray and ALVESCO® HFA (ciclesonide) Inhalation Aerosol, which we expect to launch commercially during 2008.

We have, from time to time, licensed our technology and patent rights to third parties. These out-licensing agreements include Schering-Plough Corporation for CLARINEX® (desloratadine); sanofi-aventis, formerly Aventis, for ALLEGRA® (fexofenadine HCl); and UCB Farchim S.A. and UCB S.A., referred to collectively as UCB, for XYZAL®/XUSAL™ (levocetirizine). As a result of these agreements, we earned aggregate royalties of \$47.7 million, \$33.8 million and \$51.2 million in 2007, 2006 and 2005, respectively, on sales of CLARINEX, ALLEGRA and XYZAL/XUSAL. Our out-licensing agreements also include licenses to Eisai Co. Ltd., or Eisai, for the development and commercialization in Japan of our eszopiclone product, marketed as LUNESTA in the United States, and Glaxo Group Limited, or GSK, an affiliate of GlaxoSmithKline, for the development and commercialization of our eszopiclone product for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territory primarily as LUNIVIA® brand eszopiclone for the treatment of insomnia. We will not receive royalties on sales of our eszopiclone product pursuant to either of these agreements unless and until such product is approved for commercialization by the relevant regulatory authority in the applicable market and the product is commercially introduced.

In early 2008 and 2007, our key developments included the following:

#### **Corporate Development & Licensing**

- In January 2008, we entered into an agreement with Nycomed for the exclusive U.S. distribution, development and commercialization in the United States, its territories and possessions, of Nycomed's compound ciclesonide, and products incorporating such compound, including ALVESCO HFA Inhalation Aerosol metered-dose inhaler, for use in the treatment of asthma, and OMNARIS AQ nasal spray for use in the treatment of allergic rhinitis. Under the agreement, we paid Nycomed an upfront payment of \$150.0 million in February 2008 and may be required to make subsequent payments of up to \$280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. Nycomed will also receive compensation for supplying finished product pursuant to the agreement, including a supply price for the products, which will be based on Nycomed's manufacturing costs plus a percentage of such costs, and quarterly royalty payments based on our net sales of the products.
- In December 2007, we entered into a license agreement with Bial—Portela & C<sup>a</sup>, S.A., or Bial, for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound, BIA 2-093, which we now refer to as SEP-0002093. Pursuant to the agreement, we paid Bial an upfront payment of \$75.0 million and are required to make subsequent payments upon accomplishment of various development and regulatory milestones, which could include up to an additional \$100.0 million if all milestones are met. Bial will also receive compensation for providing finished product pursuant to a supply agreement that is expected to be entered into by the parties, which will be calculated as a percentage of the average net selling price for finished tablets, and milestone payments upon FDA approval of additional indications, if any.
- In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product, which we market as LUNESTA in the United States, for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territory primarily as LUNIVIA brand eszopiclone for the treatment of insomnia. Under this agreement, we received an initial payment of \$20.0 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us \$155.0 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties that escalate upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement that is expected to be entered into by the parties.
- In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product, which we market as LUNESTA in the United States. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an initial milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

#### **Directors & Officers**

- In December 2007, we announced that Timothy J. Barberich will retire as an executive of our company prior to May 13, 2008 and plans to serve as our advisor through December 2009.

Mr. Barberich also intends to continue to serve as Chairman of our Board of Directors, contingent on his election as a director at the 2008 annual meeting of our shareholders.

- In November 2007, Lisa Ricciardi was elected as a new member of our Board of Directors.
- In October 2007, Mark Iwicki was elected to the newly-created position of Executive Vice President, Chief Commercial Officer.
- In May 2007, Adrian Adams was elected to the role of President and Chief Executive Officer. Mr. Adams previously served as our President and Chief Operating Officer and assumed the Chief Executive Officer role from Mr. Barberich.
- In March 2007, W. James O'Shea resigned as our President and Chief Operating Officer and was elected Vice Chairman. Mr. O'Shea ceased acting in this capacity on August 31, 2007. In addition, effective March 1, 2007, our board elected Adrian Adams to the positions of President and Chief Operating Officer and Andrew I. Koven to the positions of Executive Vice President, General Counsel and Corporate Secretary. The board, upon the recommendation of the nominating and corporate governance committee, also elected Mr. Adams to the Board of Directors, as a Class II director. Douglas E. Reedich, our former Senior Vice President, Legal Affairs, was employed by us through December 31, 2007 in order to ensure an orderly transition in the handling of our legal matters.

#### **Litigation and Investigations**

- In November 2007, the SEC notified us that the investigation concerning our historical stock option granting practices had been completed and that no enforcement action was being recommended.
- In October 2007, we reached a settlement with the parties to both the state and Federal derivative actions brought against us (as a nominal defendant) and certain of our current and former officers and directors related to certain stock option grants and alleged violations of Federal securities laws, that provided for the dismissal of both actions. The settlement resolved all claims and included no finding of wrongdoing on the part of any of the defendants and no cash payment other than attorneys' fees. As part of the settlement, we have adopted, and are in the process of completing the implementation of, stock option grant and other procedures that reflect developing best practices. The settlement became final and effective in January 2008 upon final approval by the state court and entry of dismissal with prejudice by the Federal court.
- In October 2007, we reached a final settlement agreement with Tharos Laboratories, Inc., or Tharos, with respect to the litigation brought against us by Tharos alleging trademark infringement, dilution, unfair competition, false advertising and false designation of origin arising out of our use of our silk luna moth design in connection with LUNESTA. As a result of this settlement agreement, the case has been dismissed.
- In June 2007, we filed in the United States District Court for the District of Massachusetts, or the Court, a Stipulation of Settlement regarding two securities class action lawsuits, or class actions, pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. The class actions, which were filed on behalf of certain purchasers of our equity and debt securities, or the plaintiffs, allege that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. The Stipulation of Settlement contains no admission of wrongdoing. Sepracor and the other defendants have always maintained and continue to believe that we did not engage in any wrongdoing or otherwise commit any violation of Federal or state securities laws or other laws. However, given the

potential cost and burden of continued litigation, we believe the settlement was in our best interests and the best interests of our stockholders. Under the terms of the Stipulation of Settlement, in June 2007 we paid into escrow \$52.5 million in settlement of the class actions and, in July 2007, received an \$18.5 million reimbursement from our insurance carriers. We recorded the litigation settlement expense of \$34.0 million, relating to this matter, during the quarter ended March 31, 2007. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow. Pursuant to the final judgment entered by the Court, the Court dismissed the class actions with prejudice, and the plaintiffs are deemed to have released all claims against us.

- In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey, L.P. and Dey, Inc., referred to collectively as Dey, alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single U.S. patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaim to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. Under the current scheduling order, trial will begin no earlier than January 12, 2009.

## **Regulatory**

- In November 2007, we announced that CMS established a product-specific billing code, or J Code, for BROVANA under the Medicare Part B benefit, which became effective on January 1, 2008. In April 2007, we announced the commercial availability of BROVANA for the treatment of COPD.
- In July 2007, we submitted a Marketing Authorization Application, or MAA, to the European regulatory authorities for LUNIVIA for the treatment of insomnia. Approval of the MAA, which is the European Union equivalent of a New Drug Application, or NDA, in the United States, would allow authorization to market LUNIVIA in the European Union. Pursuant to our agreement with GSK, we are responsible for supporting the MAA until final approval, or such earlier date mutually agreed upon by the parties, and GSK is responsible for supporting the MAA thereafter. We received a consolidated report from the reviewing MAA rapporteurs in December 2007 and responded to them in early 2008. Approval of the MAA is targeted for the fourth quarter of 2008.
- In June 2007, we announced that CMS determined that, based on its interpretation of the statutory language of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, it was required to discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and generic albuterol, which had been in place since January 2005, and instead calculate the reimbursement for XOPENEX Inhalation Solution and generic albuterol based on the blended weighted average selling price, or ASP, for the two products. This new reimbursement became effective on July 1, 2007. Using a blended weighted ASP for XOPENEX Inhalation Solution results in reimbursement for the product that is considerably lower than the published selling price for the product in the wholesaler distribution channel. The new reimbursement rate is subject to change quarterly based upon the respective contribution of commercial sales of XOPENEX Inhalation Solution and generic albuterol to the quarterly blended weighted ASP calculation. This quarterly ASP calculation is mandated by the MMA. Revenues from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of this change.

In addition, on December 29, 2007, President Bush signed into law legislation, the effect of which mandates that XOPENEX Inhalation Solution and generic albuterol be reimbursed at the lower of their stand-alone weighted ASP and the blended weighted ASP for XOPENEX Inhalation Solution and generic albuterol. The effect of this legislation is that XOPENEX Inhalation Solution will continue to be reimbursed at the blended rate and generic albuterol will be reimbursed at its stand-alone weighted ASP. The legislation goes into effect on April 1, 2008.

#### **Other Key Developments**

- In February 2008, we announced that we intend to increase our sales force capacity by at least 200 sales professionals in order to accommodate the commercialization of OMNARIS AQ and ALVESCO HFA.
- In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. As a follow up to this disclosure to CMS, our management, with the oversight of our Audit Committee, is reviewing our government pricing activities affected by the material weakness in our internal controls related to these potential errors.
- In October 2007, we announced that we had decided to reduce our sales force by approximately 300 positions. The decision was based on our evaluation of the structure, size and allocation of our direct sales force at that time and was intended to result in cost savings in fiscal year 2008. As of December 31, 2007, this sales force reduction was completed.
- In February 2007, we paid in full \$440.0 million in aggregate principal amount of outstanding 5% convertible subordinated debentures, which matured on February 15, 2007, plus approximately \$11.0 million in accrued interest.

For the year ended December 31, 2007, our total revenues and net income were \$1,225.2 million and \$58.3 million, respectively. Fiscal year 2007 was our second profitable year since inception. We have funded our operations primarily through convertible debt financings, sales of our products, license agreements for our drug compounds, and the issuance of common stock, including the exercise of stock options. We now plan to finance our operations primarily with cash generated from product sales. In order to achieve continued profitability, we will need to continue to grow our product sales. The rate of our future sales growth depends, in part, upon our ability to successfully develop or acquire and commercialize new products and/or product candidates.

Our future success is also highly dependent on obtaining and maintaining patent protection for our products. With respect to XOPENEX Inhalation Solution, Breath Limited, or Breath, Dey, L.P., Barr Laboratories, Inc., or Barr, and Watson Laboratories, Inc., or Watson, have each filed an Abbreviated New Drug Application, or ANDA, including Paragraph IV certifications with the FDA seeking to market a generic version of levalbuterol hydrochloride inhalation solution before our patents expire. We have commenced patent infringement litigation against Breath, Dey, L.P., and Barr, but we have decided not to commence litigation against Watson at this time as its Paragraph IV certification is limited to a patent that expires in 2021. A non-jury trial in our litigation against Breath is scheduled to begin on July 14, 2008 in the United States District Court for the District of Delaware, C.A. No. 06-113. No trial date has been set in our patent infringement litigation against Dey, L.P. or Barr.

The filing of a lawsuit for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant marketing approval to these companies. The 30-month stay against Breath's ANDA is scheduled to expire for our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution on or about March 7, 2008. In December 2007, the FDA granted tentative approval to Breath's ANDA for all three dosages. Upon expiration of that 30-month stay, the FDA could grant final approval and Breath could then commence an "at risk" distribution of

its generic levalbuterol product for those dosages notwithstanding our patents and notwithstanding that the court's decision as to the merits of the litigation will not have been rendered, unless we were able to obtain an injunction prohibiting such distribution. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stays against Dey, L.P. and Barr expire on or about July 9, 2008 and November 30, 2009, respectively. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution product prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and/or results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate and we would have to revise such guidance.

## **Background on Science**

### *Chiral Compounds*

Approximately 500 currently available drugs are chiral compounds. Chiral compounds frequently exist as mixtures of mirror-image molecules known as isomers. When a chiral compound contains equal amounts of both isomers, it is a racemic mixture, or a racemate. These two isomers are generally referred to as (S)-isomers (left) and (R)-isomers (right). While isomers have identical molecular weights and physical properties, they can show remarkable selectivity within biological systems and therefore can have different biological actions. In many cases, only one isomer of the racemic drug is responsible for the drug's efficacy. The other may be an unnecessary component or may cause side effects. Typically, in our chiral compound product development process, we separate racemic mixtures containing two isomers into compounds containing only one isomer.

### *Active Metabolites*

Drugs administered to treat diseases are sometimes transformed, or metabolized, within the body into a variety of related chemical forms known as metabolites, some of which may have therapeutic activity. Metabolites that have therapeutic activity are known as active metabolites. Active metabolites can also be synthesized in the laboratory. During preclinical and clinical testing of a parent drug, subjects are exposed to metabolites of the parent drug. Therefore, a developer of an active metabolite may be able to rely upon certain known clinical information from the parent drug in its NDA submission for the active metabolite, including safety data. In some cases, this can eliminate the need for certain clinical studies and expedite the development process of an active metabolite drug.

In contrast to traditional new drug development, the safety and efficacy of the racemates and parent drugs of our chiral compound and active metabolite pharmaceuticals under development are often well understood before clinical trials begin. Parent drugs have been successfully taken through clinical studies and may have been on the market for years. We evaluate isomers or active metabolites in an accelerated and focused manner that is designed to allow us to efficiently identify potential advantages in our candidates such as improvements in efficacy, onset of action, duration of activity, dosage, additional indications or meaningful reductions in side effects or adverse reactions.

### *New Chemical Entities*

We have significantly expanded our research efforts to look beyond single isomers and active metabolites as sources of discovering new compounds. We are actively pursuing novel chemical entity research and licensing activities focusing primarily on central nervous system disorders, respiratory diseases and other disorders and diseases.



## **Marketed Products**

### **LUNESTA**

#### *Overview*

LUNESTA brand eszopiclone is a non-benzodiazepine used for the treatment of insomnia. Symptoms of insomnia include difficulty falling asleep, awakening frequently during the night, waking up too early, an inability to fall back to sleep, or awakening feeling unrefreshed. LUNESTA is approved for long- or short-term treatment of sleep onset and sleep maintenance insomnia. LUNESTA is classified as a schedule IV controlled substance and is marketed in 1 mg, 2 mg and 3 mg film-coated tablets.

In December 2004, we received approval from the FDA for our NDA for LUNESTA. We commercially introduced LUNESTA in the United States in April 2005, and the product is currently marketed through our sales force. Our revenues from sales of LUNESTA grew to \$600.9 million in 2007 from \$565.4 million in 2006 and \$327.1 million in 2005. LUNESTA accounted for approximately 49%, 48% and 41% of our total revenues in 2007, 2006 and 2005, respectively. We expect that LUNESTA will account for a substantial portion of our revenues in 2008.

Under our original license agreement with Rhone-Poulenc Rorer SA (the predecessor to Aventis, now sanofi-aventis) for eszopiclone, dated October 1999, we are obligated to pay a 5% royalty on sales of LUNESTA in the United States and, as part of the July 2004 amendment to this agreement, we permitted Aventis, now sanofi-aventis, to assign our royalty obligation to a third party in exchange for the right to read and reference sanofi-aventis' regulatory filings related to zopiclone outside of the U.S. for the purpose of development and regulatory registration of eszopiclone outside of the United States. Aventis has assigned to us the foreign counterparts to the U.S. patent covering eszopiclone and its therapeutic use.

In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product in Japan. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an initial milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territory primarily as LUNIVIA brand eszopiclone for the treatment of insomnia. Under this agreement, we received an initial payment of \$20.0 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us \$155.0 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties that escalate upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement that is expected to be entered into by the parties. We submitted an MAA to the European regulatory authorities for LUNIVIA in July 2007. Pursuant to our agreement with GSK, we are responsible for supporting the MAA until final approval, or such earlier date mutually agreed upon by the parties, and GSK is responsible for supporting the MAA thereafter.

During 2007, we devoted significant resources to the completion of Phase IIIB/IV studies related to LUNESTA. We expect that we will continue to devote significant resources to Phase IV post-marketing studies of LUNESTA during 2008.

### *Intellectual Property Position*

We have two issued U.S. patents covering the therapeutic use of LUNESTA (eszopiclone) and another issued U.S. patent covering the compound eszopiclone and pharmaceutical formulations containing eszopiclone. The natural terms of the compound/formulation patent and one of the use patents expire in January 2012 while the natural term of the other use patent expires in August 2012. Under the Drug Price Competition and Patent Term Extension Act of 1984, known as the Hatch-Waxman Act, we have applied for a patent term extension for the compound/formulation patent. If that extension is granted, it could extend the term of the compound/formulation patent to February 14, 2014. We cannot predict whether or not the patent term extension will be granted.

The Hatch-Waxman Act also provides for a five-year period of exclusivity beginning on the date of approval of LUNESTA, during which the FDA will not approve an ANDA for any product containing eszopiclone. The FDA can receive ANDAs after four years have elapsed from the date of approval if the ANDA contains a Paragraph IV patent challenge.

### *Manufacturing and Product Supply*

We manufacture the LUNESTA active pharmaceutical ingredient, or API, at our manufacturing facility in Nova Scotia, Ontario, Canada. This facility is part of Sepracor Canada Ltd., our wholly-owned subsidiary. We also have a qualified second source for API manufacturing at Dow Chemical Inc. in Michigan. Our final tablet manufacturing and packaging takes place at Patheon, Inc., outside of Toronto, Canada, with a second Patheon site, currently used for packaging only, in Cincinnati, Ohio. Currently, Patheon is the only qualified manufacturer of finished commercial supplies of LUNESTA. Any future change to manufacturers or the manufacturing process requires regulatory approval. We seek to maintain sufficient inventories of API and finished products to protect against supply disruptions, but cannot guarantee we will not have product shortages.

## **XOPENEX INHALATION SOLUTION**

### *Overview*

XOPENEX (levalbuterol HCl) Inhalation Solution is a short-acting beta-agonist used to treat or prevent bronchospasm in children six years of age or older and adults. XOPENEX Inhalation Solution is used to relax the constricted or narrowed bronchial tubes and reduce bronchospasm in the lung. Bronchospasm occurs most commonly in patients with reversible obstructive airway disease, such as asthma, but can also occur in patients with COPD, including chronic bronchitis and emphysema, lung infections, acute bronchitis and other medical conditions. XOPENEX Inhalation Solution comes in a liquid form that is turned into a vapor-like mist in a nebulizer machine and is then inhaled. XOPENEX Inhalation Solution is marketed in 0.31 mg and 0.63 mg dosage strengths for routine treatment of children six to eleven years old, and 0.63 mg and 1.25 mg for patients twelve years of age and older. We currently sell XOPENEX Inhalation Solution in the United States through our sales force.

According to the American Lung Association, approximately 26 million Americans have been diagnosed with asthma in their lifetime. It is the most common childhood illness and affects approximately 8.6 million children in the United States under the age of eighteen.

XOPENEX Inhalation Solution revenues tend to be greater during the colder weather months, when asthma symptoms are more prevalent, thus, our first quarter and fourth quarter revenues from XOPENEX Inhalation Solution historically have exceeded those of the second and third quarters. Our revenues from sales of XOPENEX Inhalation Solution declined to \$487.2 million in 2007 from \$543.0 million in 2006 and \$410.8 million in 2005. XOPENEX Inhalation Solution accounted for approximately 40%, 46% and 51% of our total revenues in 2007, 2006 and 2005, respectively.

In June 2007, we announced that CMS determined that, based on its interpretation of the statutory language of the MMA, it was required to discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and generic albuterol, which had been in place since January 2005, and instead calculate the reimbursement for XOPENEX Inhalation Solution and generic albuterol based on the blended weighted average selling price, or ASP, for the two products. This new reimbursement became effective on July 1, 2007. Using a blended weighted ASP for XOPENEX Inhalation Solution results in reimbursement for the product that is considerably lower than the published selling price for the product in the wholesaler distribution channel. The new reimbursement rate is subject to change quarterly based upon the respective contribution of commercial sales of XOPENEX Inhalation Solution and generic albuterol to the quarterly blended weighted ASP calculation. This quarterly ASP calculation is mandated by the MMA. While XOPENEX Inhalation Solution accounted for a substantial portion of our revenues in 2007, and we expect it will account for a substantial portion of our revenues in 2008, revenues from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of this change.

The CMS bundling action also resulted in an unintended increase in Medicare Part B reimbursement for generic albuterol, significantly higher than the product's ASP as publicly reported by the Medicare Part B program, creating the potential for inappropriate reimbursement incentives to influence the dispensing decisions of providers. On December 29, 2007, President Bush signed into law legislation, the effect of which mandates that XOPENEX Inhalation Solution and generic albuterol be reimbursed at the lower of their stand-alone weighted ASP and the blended weighted ASP for XOPENEX Inhalation Solution and generic albuterol. The effect of this legislation is that XOPENEX Inhalation Solution will continue to be reimbursed at the blended rate and generic albuterol will be reimbursed at its stand-alone weighted ASP. The legislation goes into effect on April 1, 2008.

#### *Intellectual Property Position*

We have one issued U.S. patent covering the active ingredient in XOPENEX HFA (levalbuterol tartrate) and five issued U.S. patents covering the approved therapeutic use of XOPENEX Inhalation Solution, expiring between January 2010 and August 2013. We have one other issued U.S. patent covering the marketed formulation of XOPENEX Inhalation Solution, expiring in March 2021.

Breath, Dey, L.P., Barr and Watson have each filed an ANDA including Paragraph IV certifications with the FDA seeking to market a generic version of levalbuterol hydrochloride inhalation solution before our patents expire. We have commenced patent infringement litigation against Breath, Dey, L.P., and Barr, but we have decided not to commence litigation against Watson at this time as its Paragraph IV certification is limited to a patent that expires in 2021. A non-jury trial in our litigation against Breath is scheduled to begin on July 14, 2008 in the United States District Court for the District of Delaware, C.A. No. 06-113. No trial date has been set in our patent infringement litigation against Dey, L.P. or Barr.

The filing of a lawsuit for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant marketing approval to these companies. The 30-month stay against Breath's ANDA is scheduled to expire for our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution on or about March 7, 2008. In December 2007, the FDA granted tentative approval to Breath's ANDA for all three dosages. Upon expiration of that 30-month stay, the FDA could grant final approval and Breath could then commence an "at risk" distribution of its generic levalbuterol product for those dosages notwithstanding our patents and notwithstanding that the court's decision as to the merits of the litigation will not have been rendered, unless we were able to obtain an injunction prohibiting such distribution. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stays against Dey, L.P.

and Barr expire on or about July 9, 2008 and November 30, 2009, respectively. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution product prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and/or results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate and we would have to revise such guidance.

#### *Manufacturing and Product Supply*

We manufacture the API for XOPENEX Inhalation Solution at our manufacturing facility in Nova Scotia, Canada. We also have a qualified second source for API manufacturing at Shasun Pharma Solutions, Ltd. (formerly known as Rhodia-Chirex, Inc.) in the United Kingdom. Catalent Pharma Solutions, LLC, or Catalent, formerly Cardinal Health, Inc., and Holopack International Corporation, or Holopack, are currently our only finished goods manufacturers of our XOPENEX Inhalation Solution. Any future change to manufacturers or the manufacturing process requires regulatory approval. We seek to maintain sufficient inventories of API and finished products to protect against supply disruptions but cannot guarantee we will not have product shortages.

### **XOPENEX HFA METERED-DOSE INHALER**

#### *Overview*

XOPENEX HFA (levalbuterol tartrate) Inhalation Aerosol, an HFA MDI, is indicated for the treatment or prevention of bronchospasm in adults, adolescents and children four years of age and older with reversible obstructive airway disease. MDIs are hand-held, pressurized canisters that deliver inhaled medications directly to the lungs. XOPENEX HFA combines levalbuterol with a propellant to produce a fine mist that delivers a specific amount of medication to a patient's lungs. XOPENEX HFA complements the XOPENEX Inhalation Solution product line and provides patients with a portable means of administering XOPENEX.

XOPENEX HFA does not contain any ozone-depleting chlorofluorocarbons, or CFCs, but instead contains a hydrofluoroalkane propellant, which is not ozone-depleting. Approximately 40% of the short-acting beta-agonist inhalers sold in the fourth quarter of 2007 contained CFC propellants, according to IMS Health information. Under provisions in the Montreal Protocol on Substances that Deplete the Ozone Layer, an international agreement that requires the phase-out of substances that deplete the ozone layer, MDIs containing CFC propellants would qualify for removal from the marketplace. In March 2005, the FDA issued its final rule for the removal of the essential use exemption for albuterol, which currently permits the use of CFC-containing albuterol inhalers notwithstanding environmental concerns. Under the rule, all production and sales of CFC-containing albuterol MDIs in the U.S. are required to cease by the end of 2008.

In 2006, production of CFC-containing albuterol inhalers began to decline as production of HFA inhalers began to increase. As of early 2007, the major producers ceased production of CFC-containing albuterol MDIs. There continues to be a transition in the short-acting beta-agonist MDI market from a predominantly generic CFC-based market to a branded HFA-based market. We expect to continue to position XOPENEX HFA as an appropriate alternative to CFC albuterol MDIs throughout this transition period.

In March 2005, we received approval from the FDA for our NDA for XOPENEX HFA. We commercially introduced XOPENEX HFA in the United States in December 2005, and the product is currently marketed through our sales force. Revenues from sales of XOPENEX HFA grew to \$74.9 million in 2007 from \$41.0 million in 2006. XOPENEX HFA accounted for approximately 6% and 3% of our total revenues in 2007 and 2006, respectively. XOPENEX HFA revenues are expected to be greater during the colder weather months, when asthma symptoms are more prevalent, thus our first quarter and fourth quarter revenues for this product are expected to exceed those of the second and third quarters. In 2008, we expect that XOPENEX HFA will account for less than 10% of our overall revenues.

### *Intellectual Property Position*

We have five issued U.S. patents covering the approved therapeutic use of XOPENEX HFA, which expire between January 2010 and August 2013. We have an issued U.S. patent covering the active ingredient in XOPENEX HFA, which expires in October 2024. We also have a non-exclusive license under certain patents owned by Minnesota Mining and Manufacturing Company, or 3M, that relate to HFA inhalation aerosol technology. The 3M patents expire between 2009 and 2017.

### *Manufacturing and Product Supply*

We manufacture the API for XOPENEX HFA at our facility in Nova Scotia, Canada. We currently have one qualified manufacturer of finished commercial supplies of XOPENEX HFA, which is 3M. Under our supply agreement with 3M, we are obligated to pay to 3M a combination of a fixed price per unit of product purchased and a percentage royalty based on our net sales of XOPENEX HFA. We have several suppliers from whom we order components that go into the manufacture of the canister. These parts are shipped to a 3M site in California for final manufacturing, which includes aerosol filling and packaging. Any future change to manufacturers or the manufacturing process requires regulatory approval. We seek to maintain sufficient inventories of API and finished products to protect against supply disruptions but cannot guarantee we will not have product shortages.

## **BROVANA**

### *Overview*

BROVANA (arformoterol tartrate) Inhalation Solution is a long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema, and is approved for use with a nebulizer. According to the National Center for Health Statistics, COPD is the fourth leading cause of death in the United States, and in 2004, approximately 12 million adults in the United States were reported to have COPD. Approximately 24 million adults have evidence of impaired lung function, which may indicate that COPD is under-diagnosed, according to the National Heart, Lung, and Blood Institute, or NHLBI. COPD is a slowly progressive disease of the airways that is characterized by a gradual loss of lung function.

In October 2006, we received approval from the FDA for our NDA for BROVANA. We commercially introduced BROVANA in the United States in April 2007, and the product is currently marketed through our sales force. In November 2007, we announced that CMS established a product-specific billing code, or J Code, for BROVANA under the Medicare Part B benefit, which became effective on January 1, 2008. Revenues from sales of BROVANA were \$14.3 million in 2007 and accounted for approximately 1% of our total revenues. In 2008, we expect that BROVANA will account for less than 5% of our overall revenues.

### *Intellectual Property Position*

We have four issued U.S. patents covering the approved therapeutic use of BROVANA Inhalation Solution, all expiring in April 2012. We have applied for a patent term extension of 745 days for one of these patents. We also have four issued U.S. patents covering the active ingredient of BROVANA, one of which expires in November 2016, and the other three in November 2021.

### *Manufacturing and Product Supply*

We manufacture the API for BROVANA at our manufacturing facility in Nova Scotia, Canada. Catalent is currently our only qualified manufacturer of finished commercial supplies of BROVANA. Any future change to manufacturers or the manufacturing process requires regulatory approval. We

seek to maintain sufficient inventories of API and finished products to protect against supply disruptions but cannot guarantee we will not have product shortages.

## **Competition**

We face intense competition in the sale of our current products, and expect to face intense competition in the sale of any future products we sell. If we are unable to compete effectively, our financial condition and results of operations could be materially adversely affected because we may not achieve our product revenue objectives and because we may use our financial resources to seek to differentiate ourselves from our competition. Large and small companies, academic institutions, governmental agencies and other public and private organizations conduct research, seek patent protection, develop and acquire products, establish collaborative arrangements for product development and sell or license products in competition with us. Many of our competitors and potential competitors have substantially greater resources, manufacturing and sales and marketing capabilities, research and development staff and production facilities than we have. The fields in which we compete are subject to rapid and substantial technological change. Our competitors may be able to respond more quickly to new or emerging technologies or to devote greater resources to the development, manufacture and marketing of new products and/or technologies than we can. As a result, any products and/or technologies that we develop may become obsolete or noncompetitive before we can recover expenses incurred in connection with their development.

### *LUNESTA*

For insomnia treatments, LUNESTA faces intense competition from established branded and generic products in several drug classes including benzodiazepines, non-benzodiazepines, melatonin agonists, select anti-depressants and others. We estimate that our existing LUNESTA prescriptions account for less than 10% of the total, annual prescriptions currently being written in the United States for insomnia pharmaceutical therapies. Furthermore, LUNESTA faces substantial competition from non-prescription, over-the-counter and dietary supplement insomnia product options. We expect that LUNESTA will face increasing competition from a generic version of AMBIEN (zolpidem tartrate), which was introduced in April 2007, a generic version of AMBIEN CR (zolpidem tartrate extended release), which could be introduced as early as March 2009, and therapies in clinical development and under FDA review for the treatment of insomnia. We may also face additional competition in the event of commercial introduction of a generic version of LUNESTA. To continue to be successful with LUNESTA, we must continue to demonstrate that LUNESTA's safety and efficacy features are superior to those of competing branded and generic products, some of which may be less expensive than LUNESTA.

### *XOPENEX FRANCHISE*

For asthma and COPD treatments, XOPENEX Inhalation Solution and XOPENEX HFA face intense competition from a variety of products. Asthma and COPD patients turn to numerous classes of drugs, including corticosteroids, long-acting beta-agonists, short-acting beta-agonists, leukotriene modifiers, anticholinergics, and others, as well as certain combinations thereof. XOPENEX Inhalation Solution and XOPENEX HFA together account for approximately 3% of the total annual prescriptions currently being written in the United States for asthma and COPD pharmaceutical therapies. XOPENEX Inhalation Solution and XOPENEX HFA also face intense competition specifically within the beta-agonist classes of asthma and COPD treatments. We estimate that our existing XOPENEX prescriptions account for approximately 10% of the total annual prescriptions currently being written in the United States for beta-agonist asthma and COPD pharmaceutical therapies.

Both mono-therapy and combination-therapy beta-agonist treatments compete directly with our XOPENEX products for the treatment of asthma and COPD. Albuterol, a short-acting beta-agonist,

has been available generically for many years. Products containing albuterol as an active ingredient are well established and sell at prices substantially lower than XOPENEX Inhalation Solution and XOPENEX HFA. XOPENEX HFA also faces direct competition from CFC-containing albuterol MDIs and branded HFA albuterol MDIs. With the phase-out of CFC albuterol MDI products required by the end of December 2008, we expect that competition from branded HFA MDIs will increase substantially. Furthermore, as a consequence of the ongoing commercialization of BROVANA, prescription levels for XOPENEX Inhalation Solution may be adversely affected to the extent that a significant number of physicians prescribe BROVANA, which could reduce the need for concomitant XOPENEX products. We may also face additional competition in the event of the commercial introduction of generic versions of our XOPENEX products.

To be successful with our XOPENEX products, we must demonstrate that the efficacy and safety features of these drugs outweigh the higher price as compared to generic albuterol and other competing products and that these attributes differentiate these products from other asthma and COPD treatments, including beta-agonist asthma and COPD treatments.

### *BROVANA*

For COPD treatments solely, BROVANA faces competition from a variety of products. Competitive products include all products used in the treatment of COPD. COPD patients turn to numerous classes of drugs including anticholinergics, corticosteroids, mukolytics, long-acting beta-agonists, short-acting beta-agonists, theophyllines and others. We estimate that our existing BROVANA prescriptions account for less than 1% of the total annual prescriptions currently being written in the United States for COPD pharmaceutical therapies, and less than 1% of beta-agonist COPD pharmaceutical therapies specifically. Even though BROVANA is a nebulized product, it also faces competition from long-acting beta-agonists and anticholinergics delivered by MDI and dry-powder inhaler. BROVANA also competes with combination therapy products used for COPD. In the fourth quarter of 2007, PERFOROMIST, a direct competitor with BROVANA, was launched, which we anticipate may impact adversely BROVANA's prescription levels. To be successful with BROVANA, we must demonstrate that patients with COPD will benefit by using BROVANA.

### *OMNARIS AQ*

If and when it is commercialized, OMNARIS AQ, a corticosteroid nasal spray, will compete with perennial and seasonal allergic rhinitis treatments, and will face competition from oral antihistamines, intranasal antihistamines, intranasal decongestants, other intranasal corticosteroids, intranasal mast cell stabilizers and antileukotrienes. To be successful with OMNARIS AQ, we must demonstrate that OMNARIS AQ's safety and efficacy features are superior to those of competing branded and generic products, some of which may be less expensive than OMNARIS AQ and may be available without a prescription. We may also face additional competition in the event of commercial introduction of a generic version of OMNARIS AQ.

For all of our products, we need to demonstrate to physicians, patients, and third-party payors that the cost of our product is reasonable and appropriate in light of its safety, efficacy, and health care benefits, each as compared to other competing products. In addition, if competitors introduce new products or develop new processes or new information about existing products, then our products, even those protected by patents, may be replaced in the marketplace or we may be required to lower our prices.

## Research and Development

Our research and development activities are primarily directed toward discovering and developing potentially improved versions of widely-prescribed drugs and new chemical entities unrelated to existing compounds.

Our total research and development expenses were \$263.8 million, \$163.5 million and \$144.5 million for 2007, 2006 and 2005, respectively.

Our spending during the past three years has centered on advancing our drug candidates through clinical trials. We expend the majority of funds on programs closest to NDA submission. Over the three-year period ended December 31, 2007, our principal research and development programs were (1) the post-NDA development of LUNESTA, for which we received FDA approval in December 2004, and which we commercially introduced in April 2005; (2) the development of XOPENEX HFA, for which we received FDA approval in March 2005, and which we commercially introduced in December 2005; (3) the development of BROVANA, for which we received FDA approval in October 2006, and which we commercially introduced in April 2007; (4) Phase I studies of SEP-225289, a serotonin, norepinephrine and dopamine reuptake inhibitor, or SNDRI, for the treatment of major depressive disorder, or MDD; and (5) Phase I studies of SEP-227162, a serotonin, norepinephrine reuptake inhibitor, or SNRI for the treatment of depression and/or anxiety.

In 2008, we intend to significantly increase research and development expenditures over 2007. We expect our principal research and development activities will relate to the following programs (which are described in more detail below); (1) drug discovery; (2) LUNESTA; (3) SEP-225441; (4) ciclesonide pipeline; (5) SEP-225289, and; (6) SEP-0002093.

### Drug Development Programs

All of our drug candidates require significant research, development, successful preclinical and/or clinical testing, regulatory approval and a commitment of significant additional resources prior to commercialization.

#### *Respiratory*

**XOPENEX HFA.** In 2008, we expect to commence a Phase IV pediatric study of XOPENEX HFA.

**BROVANA.** The FDA approved BROVANA in October 2006, which we commercially introduced in April 2007, and has mandated a large Phase IV safety study and a pediatric Phase IV asthma study. In late 2007, we commenced the pediatric asthma study and we expect to commence the safety study in late 2008 or early 2009.

**ALVESCO inhalation solution.** Under our agreement with Nycomed, we are responsible for the clinical development of ALVESCO inhalation solution. ALVESCO inhalation solution is an innovative inhaled corticosteroid providing asthma control in all patient groups regardless of asthma severity. ALVESCO inhalation solution is in the pre-Investigational New Drug Application, or IND, planning stage.

**OMNARIS HFA.** Under our agreement with Nycomed, we are responsible for the technical and clinical development of OMNARIS HFA. OMNARIS HFA is an innovative intranasal steroid formulation being developed for therapeutic effects in seasonal as well as perennial allergic rhinitis. The OMNARIS HFA program has completed Phase I and Phase II clinical trials and is in the planning stage for Phase III trials.



**ALVESCO in combination with a long-acting beta-agonist.** Under our agreement with Nycomed, we are responsible for the clinical development of ALVESCO in combination with a long-acting beta-agonist. Prior to entering into our agreement, Nycomed completed various preclinical and early stage clinical studies. We are in the process of evaluating the next steps for the development of this product.

#### *Central Nervous System*

#### **LUNESTA / LUNIVIA (eszopiclone).**

Together with our collaboration partners, we are currently seeking to develop and market our eszopiclone product outside the United States, and we are seeking to provide further clinical support of our LUNESTA marketing efforts in the United States.

#### **Eszopiclone—Europe**

In July 2007, we submitted an MAA for LUNIVIA with the regulatory authorities in the European Union, or E.U. We received a consolidated report from the reviewing MAA rapporteurs in December 2007 and responded to them in early 2008. Approval of the MAA is targeted in the fourth quarter of 2008. We also have an ongoing European clinical study of eszopiclone for the treatment of patients with depression.

#### **Eszopiclone—Japan**

In the United States, we completed a Phase I pharmacokinetic study of eszopiclone for the treatment of insomnia for use in connection with the registration with the Japanese regulatory authorities that we initiated in 2006. In 2006, we conducted successful regulatory meetings in Japan with regard to our plans for further study and development of eszopiclone and filed a Clinical Trial Notification, or CTN, in Japan, which is equivalent to an IND in the United States. During 2007, we completed a Phase I pharmacokinetic study for the treatment of insomnia in the elderly in Japan. In the third quarter of 2007, we established a joint development committee with Eisai, our eszopiclone collaboration partner in Japan. This committee has developed plans and committed resources required to complete the remaining development necessary in connection with the filing of the Japanese NDA equivalent. The major outstanding component of the Japanese development program is the completion of two clinical studies in Japan. The CTN transfer to Eisai and subsequent initiation of these clinical trials are targeted for the third quarter 2008.

#### **LUNESTA—United States**

During 2008, we expect to commence a human pediatric study of LUNESTA in response to an FDA request, in addition to completing a Phase IV study on the use of LUNESTA for the treatment of insomnia in the elderly.

**SEP-225289** is an SNDRI for the treatment of MDD. SEP-225289 has been shown in preclinical studies to be a potent and balanced reuptake inhibitor of serotonin, norepinephrine and dopamine, which are three neurotransmitters associated with depression. While there are currently no triple reuptake inhibitors on the market, preclinical studies suggest that a triple mechanism of action may provide a profile superior to those of currently marketed antidepressants. In 2006, we completed a Phase I, single-blind, randomized, placebo-controlled safety, tolerability and pharmacokinetic clinical study. In late 2007, we initiated a Phase II, proof-of-concept study for the use of SEP-225289 in patients with depression.

**SEP-227162** is an SNRI for the treatment of depression and/or anxiety. In 2006, we filed an IND for SEP-227162, and completed Phase I studies in 2007. In the second half of 2008, we expect to

participate in an end of Phase II meeting with the FDA, and we are currently targeting the initiation of Phase III in 2009.

**SEP-225441** is a GABA<sub>A</sub> agonist and potent anxiolytic in preclinical models. Clinical Phase I studies were initiated in Europe in 2007. In the fourth quarter of 2007, we submitted an IND to the FDA and initiated a Phase II generalized anxiety disorder study. We are currently enrolling patients for this study.

**SEP-225432** is an SNDRI for the treatment of MDD and has been shown in preclinical studies to be a potent and balanced reuptake inhibitor of serotonin, norepinephrine and dopamine, which are three neurotransmitters associated with depression. While there are currently no triple reuptake inhibitors on the market, preclinical studies suggest that a triple mechanism of action may provide a profile superior to those of currently marketed antidepressants. We submitted an IND in December 2007 and expect to initiate a first-in-man clinical study in the first quarter of 2008.

**SEP-225425** is an SNDRI for the treatment of MDD and has been shown in preclinical studies to be a potent and balanced reuptake inhibitor of serotonin, norepinephrine and dopamine, which are three neurotransmitters associated with depression. While there are currently no triple reuptake inhibitors on the market, preclinical studies suggest that a triple mechanism of action may provide a profile superior to those of currently marketed antidepressants. We submitted an IND in December 2007 and expect to initiate a first-in-man clinical study in the first quarter of 2008.

**SEP-0002093**, formerly BIA 2-093, is the compound we recently licensed from Bial. Under our agreement with Bial, we are responsible for further developing SEP-0002093, filing an NDA with the FDA and seeking regulatory approval in Canada. SEP-0002093 is a new chemical entity which is intended to offer patients suffering with partial epilepsy additional control of their seizures and improved quality of life. Bial has completed a Phase III program in Europe for the adjunctive treatment of epilepsy. Bial and Sepracor representatives attended a pre-NDA meeting with the FDA in January 2008. The remaining NDA submission timeline is dependent upon the quality and completeness of the Bial-derived preclinical and clinical data set. We anticipate submitting the NDA in late 2008 or in early 2009.

### **Drug Discovery Programs**

All of our drug candidates require significant research, development, successful preclinical and/or clinical testing, regulatory approval and a commitment of significant additional resources prior to commercialization.

We are continuing our research efforts for novel compounds for treatment of CNS disorders. In these programs, we are seeking to discover novel compounds, unrelated to existing compounds, which we believe may have the potential to provide benefits over existing treatments or address unmet medical needs.

Blocking the reuptake of certain brain neurotransmitters has been demonstrated to lead to effective treatments for mood and anxiety disorders. These have traditionally focused on serotonin and norepinephrine. Dopamine is a third neurotransmitter involved in the regulation of mood and attention. We recently advanced SEP-225432 and SEP-225425 with triple reuptake blocking mechanisms to our clinical program as additional lead product candidates. These candidates block reuptake of dopamine, norepinephrine and serotonin thus having the potential to address mood and anxiety disorders through incorporation of the dopamine blockade.

We are currently evaluating selective agonists that bind to the  $\alpha_2$  and  $\alpha_3$  subunits of the GABA<sub>A</sub> (gamma-aminobutyric acid) receptor, which we believe may have utility in treating anxiety without the sedation typically associated with the GABA<sub>A</sub> complex.

DAAOIs, or D-amino acid oxidase inhibitors, may offer therapeutic potential for treatment of cognitive disorders, schizophrenia and pain. We have been evaluating DAAOIs and our discovery program has identified SEP-227900 as well as other leads that may be applicable for treating different CNS disorders.

#### **Partnered Research**

**ACADIA Pharmaceuticals.** In January 2005, we entered into a collaboration agreement with ACADIA Pharmaceuticals, Inc., or ACADIA, for the development of new drug candidates targeted toward the treatment of CNS disorders. This agreement expired pursuant to its terms in January 2008, and we are no longer pursuing the development of the drug candidates subject to this agreement.

From time to time, we engage in collaborations, sponsored research agreements, and other development arrangements with third parties, including academic researchers and institutions.

#### **Partnered Products**

##### *Out-Licensed Patents*

Royalty revenues from our out-licensing agreements for certain patents we own were \$47.7 million, \$33.8 million and \$51.2 million for the years ended December 31, 2007, 2006 and 2005, respectively. Our royalty revenues currently come primarily from sales in the antihistamine market. The antihistamine products for which we receive royalties face intense competition from over-the-counter products, such as CLARITIN® and ZYRTEC®, which in November 2007 was approved by the FDA for sale without a prescription, and generic prescription antihistamine products. This competition has a direct impact on our ability to earn royalties in this market. Additionally, there is uncertainty relating to possible changes in the market with much discussion about other prescription allergy products possibly being sold without a prescription. Finally, there is a possibility that companies that produce generic drugs may succeed in their patent challenges relating to drugs for which we receive royalties and other drugs with large market share. This could result in the introduction of other generic equivalents, which may increase price competition among antihistamines and lower market share for the branded drugs.

**sanofi-aventis for Fexofenadine HCl.** In July 1993, we licensed to Hoechst Marion Roussel, Inc., now sanofi-aventis (formerly Aventis), our U.S. patent rights covering fexofenadine hydrochloride, or HCl. In October 1996, Aventis commercially introduced ALLEGRA, which is fexofenadine HCl. Since March 1, 1999, we have been entitled to receive royalties on fexofenadine product sales in countries where we have patents related to fexofenadine. In February 2001, we began earning royalties on fexofenadine sales in the U.S. However, since the introduction of a generic version of ALLEGRA in the United States during the third quarter of 2005, we have ceased to earn royalties on United States sales of ALLEGRA. We are currently receiving royalties from sanofi-aventis for sales of ALLEGRA in Japan, Canada and Australia and in certain E.U. member states.

**Schering-Plough Corporation for Desloratadine.** In December 1997, we licensed to Schering-Plough Corporation, or Schering-Plough, exclusive worldwide rights to our patents and patent applications relating to desloratadine, an active-metabolite of loratadine, which is marketed by Schering-Plough as CLARITIN. In January 2002, Schering-Plough commercially introduced CLARINEX brand desloratadine 5 mg tablets for the treatment of seasonal allergic rhinitis, or SAR, in adults and children twelve years of age and older. In February 2002, Schering-Plough received FDA approval to market CLARINEX tablets for the treatment of chronic idiopathic urticaria, or CIU, in adults and children twelve years of age and older. Under the terms of our license agreement with Schering-Plough, we are currently receiving royalties on sales of CLARINEX in countries in which we hold patents.

**UCB for Levocetirizine.** In February 2006, we entered into a license agreement with UCB S.A. relating to levocetirizine. Under this agreement, we have exclusively licensed to UCB S.A. all of our patents and patent applications in the United States regarding levocetirizine and royalties are payable to us on United States sales of levocetirizine products. In September 2006, UCB and sanofi-aventis announced they entered into an agreement to co-promote XYZAL in the United States. In February 2008, UCB announced that the FDA approved its NDA for XYZAL 0.5 mg/ml solution. XYZAL tablets received approval in May 2007. Pursuant to our agreement with UCB Farchim S.A., we also earn royalties on sales of levocetirizine outside of the United States. Levocetirizine is currently marketed by UCB under the brand names XYZAL and XUSAL in the E.U. for treatment of symptoms of seasonal and perennial allergic rhinitis, persistent allergic rhinitis and CIU in adults and children six years of age and older.

#### *Out-Licensed Products*

**Eisai for Eszopiclone.** In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product in Japan. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an initial milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

**GSK for Eszopiclone.** In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territory primarily as LUNIVIA brand eszopiclone for the treatment of insomnia. Under this agreement, we received an initial payment of \$20.0 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us \$155.0 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties that escalate upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement that is expected to be entered into by the parties.

#### *In-Licensed Product and Exclusive Distributor Agreement*

**Bial for Anti-Epileptic Compound** In December 2007, we entered into a license agreement with Bial for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound, BIA 2-093, which we subsequently renamed SEP-0002093. Pursuant to the agreement, we paid Bial an upfront payment of \$75.0 million and are required to make subsequent payments upon accomplishment of various development and regulatory milestones, which could include up to an additional \$100.0 million if all milestones are met. Bial will also receive compensation for providing finished product pursuant to a supply agreement that is expected to be entered into by the parties, which will be calculated as a percentage of the average net selling price for finished tablets, and milestone payments upon FDA approval of additional indications, if any.

**Nycomed for Ciclesonide Compound.** In January 2008, we entered into an agreement with Nycomed for the exclusive U.S. distribution, development and commercialization in the United States, its territories and possessions of Nycomed's compound ciclesonide, and products incorporating such compound, including ALVESCO HFA Inhalation Aerosol metered-dose inhaler, for use in the treatment of asthma, and OMNARIS AQ nasal spray for use in the treatment of allergic rhinitis. Under the agreement, we paid Nycomed an upfront payment of \$150.0 million in February 2008 and may be required to make subsequent payments of up to \$280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. Nycomed will also receive

compensation for supplying finished product pursuant to the agreement, including a supply price for the products, which will be based on Nycomed's manufacturing costs plus a percentage of such costs, and quarterly royalty payments based on our net sales of the products.

## **Marketing and Sales**

We currently market and sell our products through our sales force, and we out-license certain of our intellectual property rights in exchange for royalties. We believe that in certain situations, partnering arrangements allow us to use the partner's development and marketing expertise to market our drug candidates more quickly. We currently have partnering agreements for our products and intellectual property with Schering-Plough, sanofi-aventis, UCB, Eisai and GSK. In each of these partnering arrangements, we are dependent upon the efforts, including marketing and sales efforts for approved products, of our partners, and these efforts may not be successful.

We have established a sales force to market XOPENEX Inhalation Solution, our short-acting bronchodilator; LUNESTA, for the treatment of insomnia; XOPENEX HFA, our short-acting bronchodilator in an MDI formulation; and BROVANA, our long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema. In October 2007, we announced that we had decided to reduce our sales force by approximately 300 positions. The decision was based on our evaluation of the structure, size and allocation of our direct sales force at that time and was intended to result in cost savings in fiscal year 2008. As of December 31, 2007, this sales force reduction was complete. We now have approximately 1,600 sales professionals who market our drugs to primary care physicians, psychiatrists, pediatricians, pulmonologists, allergists, sleep specialists and hospitals in the United States. In January 2008, we acquired exclusive U.S. distribution rights to two products that have been approved by the FDA, OMNARIS AQ and ALVESCO HFA, and we intend to increase our sales force capacity by at least 200 sales professionals through the expansion of our direct sales force or the services of a contract sales organization in order to accommodate the commercialization of these two products.

Our products are primarily sold directly to pharmaceutical wholesalers, retail pharmacy chains and home health care organizations. There are a limited number of major wholesalers and retail chains as a result of significant consolidation among companies in the industry. Therefore, as is typical in the pharmaceutical industry, a few customers provide a significant portion of our overall revenues. Also, our terms of sale typically allow for the return of unused product up to one year after product expiration.

Product sales of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA to McKesson Corp, Cardinal Health, Inc., AmerisourceBergen Corp. and CVS Caremark Corp. represented approximately 31%, 29%, 17% and 10%, respectively, of our revenues in 2007. No other customer accounted for more than 10% of our revenues in 2007.

We currently warehouse and ship all of our products through UPS Supply Chain Solutions, a division of United Parcel Services, Inc., through locations in Louisville, Kentucky and outside of Reno, Nevada. Our expectation for 2008 and beyond is to continue to distribute all of our products through one third-party vendor with at least two locations.

In 2008, we expect sales and marketing expenses to increase over 2007 as a result of the expected commercial introduction of OMNARIS AQ in the first half of 2008 and the expected commercial introduction ALVESCO HFA in the second half of 2008, including the anticipated increase in our sales force capacity.

## **Manufacturing**

We prepare certain of our drug compounds for research purposes primarily at our laboratories in Marlborough, Massachusetts. We also own and operate a current Good Manufacturing Practices compliant, or GMP-compliant, 50,000 square foot fine chemical manufacturing facility in Windsor, Nova Scotia, which we believe has sufficient capacity to support the production of our product candidates in quantities required for our clinical trials. If we successfully develop and receive regulatory approval for additional product candidates, we will need to either manufacture the drugs ourselves or rely on third parties for manufacturing. While we believe that we have the capability to scale up our manufacturing process to support the production in commercial quantities of certain of the drugs that we intend to market and sell directly, we contract out to third-party manufacturers the production of a substantial portion of those drugs. See the discussions above for specific information on the manufacture of our marketed products.

We have established a quality assurance/quality control program to ensure that our products and product candidates are manufactured in accordance with applicable regulations. We require that our contract manufacturers and collaboration partners adhere to current GMP. The facilities of our contract manufacturers and collaboration partners must pass regular post-approval FDA inspections. The FDA or other regulatory agencies must approve the processes and the facilities that may be used for the manufacture of any of our potential products.

## **Government Regulation**

### *Government Approval Process*

We, our collaboration partners and our customers, are required to obtain the approval of the FDA and similar health authorities in foreign countries, to test clinically and sell commercially, pharmaceuticals and biopharmaceuticals for human use.

Human therapeutics are generally subject to rigorous preclinical and clinical testing. The standard process required by the FDA before a drug may be marketed in the United States includes:

- preclinical laboratory tests and animal studies of toxicity and, often, carcinogenicity;
- submission to the FDA of an IND application, which must be accepted before human clinical trials may commence;
- adequate and well-controlled human clinical trials to establish safety and efficacy of the drug for its intended indication;
- submission to the FDA of an NDA; and
- FDA acceptance and approval of the NDA prior to any commercial sale or shipment of the drug.

We sometimes attempt to shorten the regulatory approval process of our drug candidates by relying on preclinical and clinical toxicology data with respect to a parent drug.

Typically, clinical evaluation involves a three-phase process. In Phase I, the initial introduction of the drug to humans, the drug is tested for safety, or adverse effects, dosage tolerance, absorption, distribution, metabolism and excretion. Phase II involves studies in a limited patient population to:

- determine the efficacy of the drug for specific targeted indications;
- determine dosage tolerance and optimal dosage; and
- identify possible adverse effects and safety risks.

When a compound is found to be effective and to have an acceptable safety profile in Phase II evaluations, Phase III trials are undertaken to further evaluate clinical efficacy and to test further for safety within an expanded patient population at geographically dispersed clinical study sites. The process of completing clinical testing, obtaining FDA regulatory approval and commencing commercial marketing takes a number of years. We may not successfully complete Phase I, Phase II or Phase III testing within any specified time period, if at all, with respect to any of our products subject to this testing. Even if we successfully complete clinical testing and the FDA accepts an NDA for filing, the FDA may determine not to approve an NDA. Furthermore, even if an NDA is approved, the FDA may not accept our evidence that a particular product meets our claims of superiority.

#### *Other Regulations Relating to the Sale of Pharmaceuticals*

FDA regulations pertain not only to health care products, but also to the processes and production facilities used to produce such products. Although we have designed the required areas of our facilities in the United States and Canada to conform to current GMP, the FDA will not review the facilities for compliance until we produce a product for which we are seeking marketing approval. Environmental legislation provides for restrictions and prohibitions on releases or emissions of various substances produced in, and waste by-products from, our operations.

The Controlled Substances Act imposes various registration, record-keeping and reporting requirements, procurement and manufacturing quotas, labeling and packaging requirements, security controls and a restriction on prescription refills on certain pharmaceutical products. A principal factor in determining the particular requirements of this Act, if any, applicable to a product is its actual or potential abuse profile. A pharmaceutical product may be listed as a Schedule II, III, IV or V substance, with Schedule II substances considered to present the highest risk of substance abuse and Schedule V substances the lowest. Eszopiclone, the active drug substance in LUNESTA, has been scheduled under the Controlled Substances Act as a Schedule IV substance. Prescriptions for Schedule IV substances may not be filled or refilled more than six months after they are written and they may not be refilled more than five times unless they are renewed. Schedule IV substances are also subject to special handling procedures relating to storage, shipment, inventory control and disposal. In addition to Federal scheduling, LUNESTA is subject to state controlled substance regulation, and may be placed in more restrictive state schedules than those determined by the U.S. Drug Enforcement Agency and FDA. To date, LUNESTA has not been placed in a more restrictive schedule by any state.

The FDA also imposes requirements relating to the marketing of drug products after approval, including requirements relating to the advertising and promotion of drug products to health care professionals and consumers and the reporting to the FDA of adverse drug experiences known to companies holding approved applications. Our failure to adhere to these requirements could lead to regulatory action by the FDA. Information reported to the FDA in compliance with these requirements could cause the FDA to withdraw drug approval or to require modification of labeling, for example, to add warnings or contraindications. The FDA has the statutory authority to seek judicial remedies and sanctions and to take administrative corrective action for violation of these and other FDA requirements and standards.

We are also subject to various Federal and state laws pertaining to health care fraud, including anti-kickback laws and false claims laws. Anti-kickback laws make it illegal for a prescription drug manufacturer to solicit, offer, receive, or pay any remuneration in exchange for, or to induce, the utilization of products or services reimbursed by a Federal or state health care program, including the purchase or prescribing of a particular drug. False claims laws prohibit anyone from knowingly and willingly presenting, or causing to be presented for payment to third-party payors, including Medicare and Medicaid, false or fraudulent claims for reimbursed drugs or services, claims for items or services not provided as claimed, or claims for medically unnecessary items or services. Penalties for violations

of health care fraud or false claims laws can include disgorgement of profits, fines, and exclusion from Federal health care programs such as Medicare.

The cost of pharmaceutical products is continually being investigated and reviewed by various government agencies, legislative bodies and private organizations in the United States and throughout the world. In the United States, most states have enacted legislation permitting, or even requiring, a dispensing pharmacist to substitute a different manufacturer's generic version of a pharmaceutical product for the one prescribed.

### *Reimbursement*

In the United States and other countries in which we sell our products, sales of drug products are dependent in part on the availability of reimbursement by third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the reimbursements paid for drugs and other medical products and services. We cannot provide assurance that any of our products will be considered cost effective by payors or that reimbursement will be available or will be sufficient to allow us to sell our products on a competitive and profitable basis.

Two principal payors in the United States are Medicaid and Medicare. Medicaid is a Federal and state entitlement program that pays for medical assistance for certain individuals and families with low incomes and resources and who meet other eligibility requirements. Medicaid became law in 1965 and is jointly funded by the Federal and state governments (including the District of Columbia and the territories) to assist states in furnishing medical assistance to eligible needy persons. Medicaid is the largest source of funding for medical and health-related services for America's indigent population.

Our drugs are generally eligible for reimbursement under Medicaid and are, therefore, subject to rebates under the Medicaid Drug Rebate Program established by the Omnibus Budget Reconciliation Act of 1990. Under the Medicaid Drug Rebate Program, we pay a rebate to each participating state agency for each unit of our product reimbursed by Medicaid. The basic amount of the rebate for each product is the greater of 15.1% of the AMP of that product, or the difference between AMP and the best price available from us to any non-excluded customer. The rebate amount also includes an inflation adjustment if AMP increases faster than a specified inflation index. The rebate amount is calculated quarterly based on our reports of our current AMP and best price for each of our products to CMS. AMPs and best price may be recalculated after they are initially submitted based on the availability of additional data or because of additional analysis of prices that have been reported.

In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. A more detailed description of our notification to CMS is found in the "Explanatory Note" of this Form 10-K. As a result of these errors, our management, with the oversight of our Audit Committee, is reviewing our government pricing. Based on the results of the review, we concluded our previously issued financial statements could no longer be relied upon and that we needed to restate our financial statements for the years ended December 31, 2006 and 2005 and the quarters ended March 31, June 30 and September 30, 2007 and 2006 to reduce the amount of product revenue earned during such periods. Depending on the final outcome of the review, we may be required to revise the prices reported under the Medicaid rebate and other programs and pay the corresponding additional rebate amounts or other amounts that may be due. We may also be subject to penalties.

Several state Medicaid programs have implemented Preferred Drug Lists, or PDLs, and more states may adopt this practice. Products placed on a state Medicaid program's PDL are not subject to restrictions on their utilization by Medicaid patients, such as the need to obtain authorization prior to prescribing. If our drugs are not included on Medicaid PDLs, use of our drugs in the Medicaid program may be adversely affected. In some states that have adopted PDLs, we have been, and may



continue to be, required to provide substantial supplemental rebates to state Medicaid authorities in order for our drugs to be included on the PDL.

Pharmaceutical manufacturers, as a condition of participation in the Medicaid Drug Rebate Programs, must enter into an agreement with the Secretary of the Department of Health and Human Services to participate in the 340B program, enacted by the PHS Act. Under the 340B programs pharmaceutical manufacturers are required to extend discounts based on the Medicaid rebate to a variety of health care entities referred to as covered entities. These covered entities include health care providers that receive health services grants from the PHS, as well as certain hospitals that serve a disproportionate share of Medicare and Medicaid beneficiaries.

Section 603 of the Veteran's Health Care Act of 1992 requires manufacturers of covered drugs to enter into a master agreement with the Secretary of the Department of Veteran Affairs, or VA, in order to have its drugs covered under Medicaid. The master agreement requires the manufacturer to make its products available for federal procurement by listing them on the Federal Supply Schedule. In addition, the master agreement requires the manufacturer to enter into a Pharmaceutical Pricing Agreement, or PPA, with the VA. Under the PPA, the manufacturer agrees to sell its drugs to the "Big Four" federal agencies—the VA, the Department of Defense, the PHS and the Coast Guard—at or below a Federal Ceiling Price, which is set at 76% of a calculation called the Non-Federal Average Manufacturer Price (non-FAMP), minus an additional discount.

Another source of reimbursement for drug products is state Pharmaceutical Assistance Programs, or SPAPs. Many of these programs were created by states to aid low-income elderly or persons with disabilities who do not qualify for Medicaid. We pay rebates to some SPAPs and, if they are considered qualified programs by CMS, the prices we provide these entities are excluded from our Medicaid best price.

The Medicare program was enacted in 1965 under the Social Security Act and provides health care coverage to aged and disabled eligible consumers. The Medicare program is comprised of several parts. In general, Medicare Part B covers physician services and many other forms of outpatient care, including some outpatient drugs. Drugs covered under Part B include those furnished incident to a physician's service and those furnished under the durable medical equipment, or DME, benefit. XOPENEX Inhalation Solution and BROVANA are eligible for coverage under Medicare Part B because each is administered via a nebulizer, which is a piece of DME covered under Part B. We established a Medicare Part B rebate program in order to increase the access by Medicare Part B beneficiaries to our XOPENEX Inhalation Solution and BROVANA products through Medicare Part B pharmacy providers.

Effective January 1, 2006, Congress enacted a prescription drug benefit known as Medicare Part D. CMS contracted with numerous Medicare Advantage Prescription Drug, or MA-PD, managed care plans and Medicare Prescription Drug Plans, or PDPs, which offer only prescription drug coverage, to deliver the drug benefit. MA-PDs and PDPs develop formularies that determine which products are covered and at what co-pay level. We pay rebates to certain Medicare Part D plans on the sale of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA.

Federal and state government agencies continue to promote efforts to reduce health care costs, including those associated with the Medicare and Medicaid programs. These efforts may include supplemental rebates and restrictions on the amounts that agencies will reimburse for the use of products.

### *Availability and Delivery of Pharmaceutical Products*

We expect debate to continue during 2008 at the Federal and state levels over the availability, delivery of, and payment for, pharmaceutical products. We believe that if certain legislation is enacted, it could have the effect of reducing prices or limiting price increases of pharmaceutical products.

At this time it is not possible to predict the extent to which we, or the pharmaceutical industry in general, might be affected by the reimbursement and pricing issues discussed above.

### *Hazardous Materials*

Our research and development activities involve the controlled use of hazardous materials, chemicals, biological materials, and various radioactive compounds. We believe that our procedures comply with the standards prescribed by state and Federal regulations; however, the risk of injury or accidental contamination cannot be completely eliminated.

### **Patents and Proprietary Technology**

#### *General*

We and our affiliates, subsidiaries and collaboration partners have filed patent applications in the United States and selected other countries relating to compositions of, formulations of, methods of making, and methods of using our drugs and drug candidates (and those for which we have rights to commercialize), and chiral synthesis and separations. In addition, we have licensed from third parties certain rights under various patents and patent applications.

To the extent that we invent or discover a new, useful and non-obvious invention and file a patent application for such invention, a composition or method-of-use patent may be issued. We are currently pursuing a policy of seeking patent protection for our drug candidates and discovery programs.

Many of the compounds that we are investigating or developing may be subject to patents held by third parties. There may be foreign equivalents to these third-party patents, the scope and expiration of which may vary from country to country. Even if we are issued a patent for the use of a single isomer or active metabolite that is currently claimed by one or more third-party patents, products based on any such patent issued to us may not be sold until all of such third-party patents expire unless a license is obtained to such third-party patents or such third-party patents are determined to be invalid, unenforceable, or not infringed by a court of proper jurisdiction. In addition, there may be pending additional third-party patent applications covering our drugs in development, which, if issued, may preclude the sale of our drug.

We have a significant number of other U.S. patents and patent applications covering composition of, methods of making and methods of using our product candidates. We may not be issued patents based on patent applications already filed or that we file in the future, and if patents are issued, they may be insufficient in scope. Patents and/or patent applications covering our product candidates would become increasingly material to our business if and when we seek to commercialize these candidates. Our ability to commercialize any drug successfully will largely depend on our ability to obtain and maintain patents of sufficient strength and scope to prevent third parties from developing and commercializing similar or competitive products.

### **Related Party**

#### *BioSphere Medical, Inc.*

In 1994, we established and independently financed BioSeptra Inc. as a subsidiary through an initial public offering of its common stock. From 1994 to 1999, the company operated as BioSeptra Inc.,

developing proprietary microsphere beads used as chromatography media in the production of pharmaceuticals.

In February 1999, BioSeptra determined that it would refocus on embolotherapy, which is the occlusion of the blood supply to fibroids and vascular defects. BioSeptra acquired a 51% interest in French-based BioSphere Medical, S.A., referred to as BioSphere France, with an option to purchase the remaining 49% interest in BioSphere France, and changed its corporate name to BioSphere Medical, Inc., or BioSphere. The acquisition enabled BioSphere to gain ownership of technology know-how and European regulatory approval of Embosphere® Microspheres. Between February 1999 and October 2001, BioSphere acquired the remaining 49% interest in BioSphere France.

In November 2004, we purchased, in a private placement, 4,000 shares of BioSphere Series A Convertible Preferred Stock, or BioSphere Series A Stock, and warrants to purchase 200,000 shares of BioSphere common stock from BioSphere for an aggregate purchase price of \$4.0 million. Each share of BioSphere Series A Stock is convertible into 250 shares of BioSphere common stock. In addition, quarterly dividends of 6% per annum are paid on the shares in either cash or additional shares of Series A Stock, at BioSphere's election.

At December 31, 2007, we owned 3,224,333 shares, or approximately 18%, of BioSphere's outstanding common stock, 4,749 shares of Series A Convertible Preferred Stock and warrants to purchase an additional 200,000 shares of common stock. Assuming conversion of our of Series A Convertible Preferred Stock of BioSphere and the exercise of our warrants, we would own approximately 23% of the outstanding common stock of BioSphere. We account for our investment in BioSphere under the equity method.

### **Employees**

On January 31, 2008, we and our wholly-owned subsidiaries employed approximately 2,277 persons. Of these 2,277 employees, approximately 230 were primarily engaged in research, development and engineering activities, 72 were primarily engaged in manufacturing, 1,600 were engaged in direct sales and 375 were primarily engaged in marketing, sales administration, legal, finance and accounting and corporate administration.

### **Investor Information**

We are a Delaware corporation and were founded in 1984. Our principal executive offices are located at 84 Waterford Drive, Marlborough, Massachusetts 01752. Our phone number is (508) 481-6700.

We maintain a web site with the address [www.sepracor.com](http://www.sepracor.com). We are not including the information contained on our web site as part of, or incorporating by reference into, this annual report. We make available free of charge on or through our web site our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and all amendments to those reports as soon as practicable after such material is electronically filed with or furnished to the SEC. In addition, we intend to disclose on our web site any amendments to, or waivers from, our code of business conduct and ethics that are required to be disclosed pursuant to rules of the SEC.

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy materials that we have filed with the SEC at the SEC public reference room located at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information on the public reference room.

Our SEC filings are also available to the public on the SEC's Internet website at [www.sec.gov](http://www.sec.gov).

## **Item 1A. Risk Factors**

You should carefully consider the risks described below in addition to the other information contained in this report, before making an investment decision. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not currently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations, financial condition or results from operations.

### **Risks Related to Our Financial Results and Our Common Stock**

*We have a history of net losses and we may not be able to generate revenues sufficient to achieve and maintain profitability on a quarterly and annual basis.*

Until the year ended December 31, 2006, we had incurred net losses each year since our inception. It is possible we will not be able to achieve profitability again or maintain profitability on a quarterly or annual basis. We expect to continue to incur significant operating expenditures to further develop and commercialize our products and product candidates and in order to allow us to otherwise expand our product portfolio through drug discovery and business development efforts. As a result, we will need to generate significant revenues in future periods to achieve and maintain profitability. We cannot provide assurance that we will be able to maintain profitability for any substantial period of time. If revenues grow more slowly than we anticipate or if operating expenses exceed our expectations or cannot be adjusted accordingly, our business, results of operations and financial condition will be materially and adversely affected. In addition, if we are unable to achieve or maintain profitability on a quarterly or annual basis, the market price of our common stock may decline.

*Almost all of our revenues are derived from sales of LUNESTA and XOPENEX Inhalation Solution and our future success depends on the continued commercial success of these products as well as our other products.*

Approximately 89% of our total revenues for the twelve months ended December 31, 2007 resulted from sales of LUNESTA and XOPENEX Inhalation Solution, and we expect that sales from these two products will continue to represent a significant majority of our revenues for the coming year. In April 2005, we commercially introduced LUNESTA as a new product in a highly and increasingly competitive market, and we cannot be certain that it will achieve continued commercial success. In addition, we do not have long-term sales contracts with our customers, and we rely primarily on purchase orders for sales of LUNESTA and XOPENEX Inhalation Solution. Reductions, delays or cancellations of orders for LUNESTA or XOPENEX Inhalation Solution could adversely affect our operating results. Additionally, revenues from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of a change in the Medicare Part B reimbursement rate. If sales of LUNESTA do not increase and if sales of XOPENEX Inhalation Solution in other markets do not offset the reduction in revenues resulting from the change in Medicare Part B reimbursement for the product, or if we do not prevail against those manufacturers seeking to market a generic version of our XOPENEX Inhalation Solution product, we may not have sufficient revenues to achieve our business plan or repay our outstanding debt, and our business will not be successful. Any other adverse developments with respect to the sale of LUNESTA or XOPENEX Inhalation Solution could significantly reduce revenues and have a material adverse effect on our ability to maintain profitability and achieve our business plan.

In December 2005, we commercially introduced XOPENEX HFA and in April 2007, we commercially introduced BROVANA. In addition, we expect to launch OMNARIS AQ and ALVESCO HFA in 2008. We cannot be certain that XOPENEX HFA, BROVANA, OMNARIS AQ or ALVESCO HFA will achieve commercial success.

With respect to XOPENEX Inhalation Solution, Breath, Dey, L.P., Barr and Watson have filed ANDAs including Paragraph IV certifications with the FDA seeking to market a generic version of levalbuterol hydrochloride inhalation solution before our patents expire. We have commenced patent infringement litigation against Breath, Dey, L.P., and Barr, but we have decided not to commence litigation against Watson at this time as its Paragraph IV certification is limited to a patent that expires in 2021. The filing of a lawsuit for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant marketing approval to these companies. The 30-month stay against Breath's ANDA is scheduled to expire for our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution on or about March 7, 2008. In December 2007, the FDA granted tentative approval to Breath's ANDA for all three dosages. A non-jury trial in our litigation against Breath is scheduled to begin on July 14, 2008 in the United States District Court for the District of Delaware, C.A. No. 06-113. No trial date has been set in our patent infringement litigation against Dey, L.P. and Barr.

Upon expiration of that 30-month stay in March 2008, the FDA could grant final approval and Breath could then commence an "at risk" distribution of its generic levalbuterol product for those dosages notwithstanding our patents and notwithstanding that the court's decision as to the merits of the litigation will not have been rendered, unless we were able to obtain an injunction prohibiting such distribution. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stays against Dey, L.P. and Barr expire on or about July 9, 2008 and November 30, 2009, respectively. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution product prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and/or results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate and we would have to revise such guidance.

With respect to BROVANA, in April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single U.S. patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaim to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. Under the current scheduling order, trial will begin no earlier than January 12, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

We cannot be certain that we will be able to continue to successfully commercialize LUNESTA and/or XOPENEX Inhalation Solution, that we will be able to successfully launch OMNARIS AQ or ALVESCO HFA, or that any of our products will be accepted in their markets. Specifically, the following factors, among others, could affect the level of success and market acceptance of our products:

- a change in the perception of the health care community of their safety and/or efficacy, both in an absolute sense and relative to that of competing products;
- the introduction of new products into the sleep or respiratory markets;
- the level and effectiveness of our sales and marketing efforts;
- any unfavorable publicity regarding these products or similar products;
- litigation or threats of litigation with respect to these products;

- a finding that our patents are invalid or unenforceable or that generic versions of our products do not infringe our patents or the “at risk” launch of generic versions of our products;
- the price of the product relative to other competing drugs or treatments;
- private insurers, such as managed care organizations, adopting their own coverage restrictions or demanding price concessions in response to state, Federal or administrative action;
- any changes in government and other third-party payor reimbursement policies and practices; and
- regulatory developments or other factors affecting the manufacture, marketing or use of these products.

***Sales of XOPENEX Inhalation Solution have been adversely affected as a result of the change in the Medicare Part B reimbursement rate, and if our strategy for responding to such change is not successful, our revenue will be further adversely affected.***

In May 2007, CMS announced that based on its interpretation of the statutory language of the MMA, it was required to discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and generic albuterol, which had been in place since January 2005, and instead calculate the reimbursement for XOPENEX Inhalation Solution and generic albuterol based on the blended weighted average selling price, or ASP, for the two products. This new reimbursement became effective on July 1, 2007. Using a blended weighted ASP for XOPENEX Inhalation Solution results in reimbursement for the product that is considerably lower than the published selling price for the product in the wholesaler distribution channel. The new reimbursement rate is subject to change quarterly based upon the respective contribution of commercial sales of XOPENEX Inhalation Solution and generic albuterol to the quarterly blended weighted ASP calculation. This quarterly ASP calculation is mandated by the MMA. Revenues from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of this change.

The bundling action also resulted in an unintended increase in Medicare Part B reimbursement for generic albuterol, significantly higher than the product’s ASP (as publicly reported by the Medicare Part B program), creating the potential for inappropriate reimbursement incentives to influence the dispensing decisions of providers. On December 29, 2007, President Bush signed into law legislation, the effect of which mandates that XOPENEX Inhalation Solution and generic albuterol be reimbursed at the lower of their stand-alone weighted ASP and the blended weighted ASP for XOPENEX Inhalation Solution and generic albuterol. The effect of this legislation is that XOPENEX Inhalation Solution will continue to be reimbursed at the blended rate and generic albuterol will be reimbursed at its stand-alone weighted ASP. The legislation goes into effect on April 1, 2008.

We estimate that as much as 20% of our XOPENEX Inhalation Solution units sold are subject to reimbursement under Medicare Part B. We have been actively contracting with home health care and retail pharmacy providers in an effort to ensure the continued availability of XOPENEX Inhalation Solution to Medicare Part B beneficiaries with reversible obstructive airway disease. If the contracting strategy for XOPENEX Inhalation Solution is not successful in maintaining as much of the current unit sales levels for the product in Medicare as commercially possible, if the blended Medicare Part B reimbursement rate for XOPENEX Inhalation Solution and generic albuterol falls to an amount where it is no longer financially feasible to market XOPENEX Inhalation Solution to Medicare Part B participants and/or if the Durable Medical Equipment Program Safeguard Contractors, or DME-PSCs, the entities responsible for overseeing the Medicare Part B prescription drug benefit for respiratory products, impose restrictive coverage policies on XOPENEX Inhalation Solution, revenue from sales of XOPENEX Inhalation Solution will be adversely affected and our financial condition and results from operations will be impaired.

***We have significant debt and we may not be able to make principal payments when due.***

As of December 31, 2007, our total debt was approximately \$720.8 million. None of our 0% Series A notes due December 2008, our 0% Series B notes due December 2010 nor our 0% notes due October 2024 restricts us or our subsidiaries' ability to incur additional indebtedness, including debt that ranks senior to the notes. The 0% notes due 2024 are senior to the Series A notes due 2008 and Series B notes due 2010. Additional indebtedness that we incur may in certain circumstances rank senior to or on parity with this debt. Our ability to satisfy our obligations will depend upon our future performance, which is subject to many factors, including factors beyond our control. The conversion prices for the 0% Series A notes due 2008 and 0% Series B notes due 2010 are \$31.89 and \$29.84, respectively. In December 2008, \$72.8 million will be due on our 0% Series A notes due 2008. On January 31, 2008, the closing sale price of our common stock was \$28.24. If the market price for our common stock does not exceed the conversion price, the holders of our outstanding convertible debt may decide not to convert their securities into common stock. For example, the holders of our 5% debentures did not convert such debentures into common stock, and on February 15, 2007, the maturity date for the 5% debentures, we repaid in cash the entire principal amount of \$440.0 million, plus \$11.0 million of accrued interest. Our 0% notes due 2024 are convertible into cash and, if applicable, shares of our common stock at a conversion price of approximately \$67.20, at the option of the holders in October 2009, 2014, 2019 and 2024, as well as under certain circumstances. We may not be able to make the required cash payments upon conversion of the 0% notes due 2024.

Historically, we have had negative cash flow from operations, and in 2006, we experienced our first full year of positive cash flow from operating activities. Unless we have sufficient cash or are able to generate sufficient operating cash flow to pay off the principal of our outstanding debt, we will be required to raise additional funds or default on our obligations under the debentures and notes. If revenue generated from sales of our products do not meet expected levels, it is unlikely that we would have sufficient cash flow to repay our outstanding convertible debt and/or make cash payments upon conversion of the 0% notes due 2024. There can be no assurance that, if required, we would be able to raise the additional funds on favorable terms, if at all.

***If we exchange debt for shares of common stock, there will be additional dilution to holders of our common stock.***

As of December 31, 2007, we had approximately \$720.8 million of outstanding debt that could be converted into common stock. In order to reduce future payments due at maturity, we may, from time to time, depending on market conditions, repurchase additional outstanding convertible debt for cash; exchange debt for shares of our common stock, warrants, preferred stock, debt or other consideration; or a combination of any of the foregoing. If we exchange shares of our capital stock, or securities convertible into or exercisable for our capital stock, for outstanding convertible debt or use proceeds from the issuance of convertible debt to fund redemption of outstanding convertible debt with a higher conversion ratio, the number of shares that we might issue as a result of such exchanges would significantly exceed the number of shares originally issuable upon conversion of such debt and, accordingly, such exchanges would result in material dilution to holders of our common stock. We cannot provide assurance that we will repurchase or exchange any additional outstanding convertible debt.

***We have identified a material weakness in our internal control over financial reporting that could adversely affect our ability to meet reporting obligations and negatively affect the trading price of our stock.***

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. Accordingly, a material weakness increases the risk that the financial information we report contains

material errors. As more fully described in Item 9A of this annual report on Form 10-K, Controls and Procedures, we have determined that we did not establish and/or maintain effective controls over the process to identify transactions with the potential to establish a new Medicaid best price, which affected the accuracy of the net revenue and product sales allowance and return accounts. Specifically, our controls over the calculation of Medicaid rebates were not designed to effectively monitor whether certain entities were appropriately exempt from the Medicaid best price calculation. Our management has determined that this control deficiency constitutes a material weakness and contributed to our conclusion on January 28, 2008 that our financial statements could no longer be relied upon and needed to be restated.

While we have taken, and will continue to take, steps to remediate the identified material weakness, these steps may not be adequate to fully remediate the material weakness. In addition, we may identify additional control deficiencies in the future that individually or in the aggregate constitute a material weakness. If we fail to adequately remediate the identified material weakness or there are other undetected or uncorrected deficiencies in our internal controls, we could fail to meet our reporting obligations, we could have material misstatements in our financial statements and, under certain circumstances, could be subject to legal liability. In addition, inferior controls could cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock.

*If the estimates we make, or the assumptions on which we rely, in preparing our financial statements prove inaccurate, our actual results may vary from those reflected in our projections and accruals.*

Our financial statements have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities, net revenues and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. We base our estimates on historical experience and on various other assumptions that we believe to be reasonable under the circumstances. We cannot provide assurance, however, that our estimates, or the assumptions underlying them, will not be materially different from actual results. For example, our royalty revenue is recognized based upon our estimates of our collaboration partners' sales during the period and, if these sales estimates are greater than the actual sales that occur during the period, our net income would be reduced. In addition, we estimate product sales allowances, including payment term discounts, government and commercial rebates and returns and other discounts. If actual amounts differ from these estimates, net income could be adversely affected. Each, in turn, could adversely affect our financial condition, results from operations and stock price.

*If sufficient funds to finance our business are not available to us when needed or on acceptable terms, then we may be required to delay, scale back, eliminate or alter our strategy for our programs.*

We may require additional funds for our research and product development programs, operating expenses, repayment of debt, the pursuit of regulatory approvals, license or acquisition opportunities and the expansion of our production, sales and marketing capabilities. Historically, we have satisfied our funding needs through collaboration arrangements with corporate partners, sales of products, and equity and debt financings. These funding sources may not be available to us when needed in the future, and, if available, they may not be on terms acceptable to us. Insufficient funds could require us to delay, scale back, eliminate or alter certain of our research and product development programs and/or commercialization efforts or to enter into license agreements with third parties to commercialize products or technologies that we would otherwise develop or commercialize ourselves. Our cash requirements may vary materially from those now planned because of factors including:

- patent developments;
- licensing or acquisition opportunities;



- drug discovery efforts;
- relationships with collaboration partners;
- the FDA regulatory process;
- expansion into foreign markets;
- litigation and government inquiries and investigations;
- our capital requirements; and
- selling, marketing and manufacturing expenses in connection with commercialization of products.

***Our long-term investments include auction rate securities that may not be accessible within the next twelve months and may experience a decline in value, which may adversely affect our liquidity and income.***

Our long-term investments as of December 31, 2007 were \$174.0 million, which includes \$99.9 million invested in highly-rated (AAA) student-loan-backed auction rate securities, of which some are associated with failed auctions in 2008. Auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than ninety days but with contractual maturities that can be well in excess of ten years. At the end of each reset period investors can typically sell at auction or continue to hold the securities at par. These securities are subject to fluctuations in fair value depending on the supply and demand at each auction.

As a result of the recent instability in the market for auction rate securities, there may be a future decline in the value of our auction rate securities. Should a decline in the value of these securities occur that is not temporary, it would result in a loss being recognized in our statement of operations, which could be material. In 2008, the funds associated with our auction rate securities that have failed auction, may not be accessible until a successful auction occurs, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured.

***Fluctuations in the demand for our products, the success and timing of clinical trials, regulatory approvals, product introductions, collaboration and licensing arrangements, any termination of development efforts and other material events will cause fluctuations in our quarterly operating results, which could cause volatility in our stock price.***

Our quarterly operating results are likely to fluctuate significantly, which could cause our stock price to be volatile. These fluctuations will depend on many factors, including:

- timing and extent of product sales and market penetration;
- timing and extent of operating expenses, including selling and marketing expenses and the costs of reducing, expanding and/or maintaining a direct sales force or attaining the services of a co-promotion partner or contract sales force;
- success and timing of regulatory filings and approvals for products developed by us or our licensing or collaborative partners;
- timing and success of product introductions, including OMNARIS AQ and ALVESCO HFA;
- changes in third-party reimbursement policies;
- introduction of competitive products into the market;
- results of clinical trials with respect to products under development;
- a finding that our patents are invalid or unenforceable or that generic versions of our products do not infringe our patents or the “at risk” launch of generic versions of our products;

- the initiation of, or adverse developments in, any judicial litigation proceedings or governmental investigations in which we are involved;
- a change in the perception of the health care and/or investor communities with respect to our products;
- success and timing of collaboration agreements for development of our pharmaceutical candidates and development costs for those pharmaceuticals;
- timing of receipt of upfront, milestone or royalty payments under collaboration or licensing agreements;
- timing and success of any business and/or product acquisitions;
- timing and success of expansion into foreign markets;
- termination of development efforts of any product under development or any collaboration agreement; and
- timing of expenses we may incur with respect to any license or acquisition of products or technologies.

*We have various mechanisms in place to discourage takeover attempts, which may reduce or eliminate our stockholders' ability to sell their shares for a premium in a change of control transaction.*

Various provisions of our certificate of incorporation and by-laws and of Delaware corporate law may discourage, delay or prevent a change of control or takeover attempt of our company by a third party that is opposed by our management and board of directors. Public stockholders who might desire to participate in such a transaction may not have the opportunity to do so. These anti-takeover provisions could substantially impede the ability of public stockholders to benefit from a change of control or change in our management and board of directors. These provisions include:

- preferred stock that could be issued by our board of directors to make it more difficult for a third party to acquire, or to discourage a third party from acquiring, a majority of our outstanding voting stock;
- classification of our directors into three classes with respect to the time for which they hold office;
- non-cumulative voting for directors;
- control by our board of directors of the size of our board of directors;
- limitations on the ability of stockholders to call special meetings of stockholders;
- inability of our stockholders to take any action by written consent; and
- advance notice requirements for nominations of candidates for election to our board of directors or for proposing matters that can be acted upon by our stockholders at stockholder meetings.

In addition, in June 2002, our board of directors adopted a shareholder rights plan, the provisions of which could make it more difficult for a potential acquirer of Sepracor to consummate an acquisition transaction.

*The price of our common stock historically has been volatile, which could cause the loss of part or all of an investment in Sepracor.*

The market price of our common stock, like that of the common stock of many other pharmaceutical and biotechnology companies, has been highly volatile. In addition, the stock market has experienced extreme price and volume fluctuations. The volatility and market prices of securities of

many pharmaceutical and biotechnology companies have been significantly affected for reasons frequently unrelated to or disproportionate to the operating performance of the specific companies. These broad market fluctuations may adversely affect the market price of our common stock. Prices for our common stock are determined in the marketplace and may be influenced by many factors, including variations in our financial results and investors' perceptions of us, and changes in recommendations by securities analysts as well as their perceptions of general economic, industry and market conditions.

#### **Risks Related to Commercialization**

*We face intense competition and many of our competitors have greater resources and capabilities than we have.*

We face intense competition in the sale of our current products, and expect to face intense competition in the sale of any future products we sell. If we are unable to compete effectively, our financial condition and results of operations could be materially adversely affected because we may not achieve our product revenue objectives and because we may use our financial resources to seek to differentiate ourselves from our competition. Large and small companies, academic institutions, governmental agencies and other public and private organizations conduct research, seek patent protection, develop and acquire products, establish collaborative arrangements for product development and sell or license products in competition with us. Many of our competitors and potential competitors have substantially greater resources, manufacturing and sales and marketing capabilities, research and development staff and production facilities than we have. The fields in which we compete are subject to rapid and substantial technological change. Our competitors may be able to respond more quickly to new or emerging technologies or to devote greater resources to the development, manufacture and marketing of new products and/or technologies than we can. As a result, any products and/or technologies that we develop may become obsolete or noncompetitive before we can recover expenses incurred in connection with their development.

#### **LUNESTA**

For insomnia treatments, LUNESTA faces intense competition from established branded and generic products in several drug classes including benzodiazepines, non-benzodiazepines, melatonin agonists, select anti-depressants, and others. We estimate that our existing LUNESTA prescriptions account for less than 10% of the total, annual prescriptions currently being written in the United States for insomnia pharmaceutical therapies. Furthermore, LUNESTA faces substantial competition from non-prescription, over-the-counter and dietary supplement insomnia product options. We expect that LUNESTA will face increasing competition from a generic version of AMBIEN (zolpidem tartrate), which was introduced in April 2007, a generic version of AMBIEN CR (zolpidem tartrate extended release), which could be introduced as early as March 2009, and therapies in clinical development and under FDA review for the treatment of insomnia. We may also face additional competition in the event of commercial introduction of a generic version of LUNESTA. To continue to be successful with LUNESTA, we must continue to demonstrate that LUNESTA's safety and efficacy features are superior to those of competing branded and generic products, some of which may be less expensive than LUNESTA.

#### **XOPENEX FRANCHISE**

For asthma and COPD treatments, XOPENEX Inhalation Solution and XOPENEX HFA face intense competition from a variety of products. Asthma and COPD patients turn to numerous classes of drugs, including corticosteroids, long-acting beta-agonists, short-acting beta-agonists, leukotriene modifiers, anticholinergics, and others, as well as certain combinations thereof. XOPENEX Inhalation Solution and XOPENEX HFA together account for approximately 3% of the total annual prescriptions

currently being written in the United States for asthma and COPD pharmaceutical therapies. XOPENEX Inhalation Solution and XOPENEX HFA also face intense competition specifically within the beta-agonist classes of asthma and COPD treatments. We estimate that our existing XOPENEX prescriptions account for approximately 10% of the total annual prescriptions currently being written in the United States for beta-agonist asthma and COPD pharmaceutical therapies.

Both mono-therapy and combination therapy beta-agonist treatments compete directly with our XOPENEX products for the treatment of asthma and COPD. Albuterol, a short-acting beta-agonist, has been available generically for many years. Products containing albuterol as an active ingredient are well established and sell at prices substantially lower than XOPENEX Inhalation Solution and XOPENEX HFA. XOPENEX HFA also faces direct competition from CFC-containing albuterol MDIs and branded HFA albuterol MDIs. With the phase-out of CFC albuterol MDI products required by the end of December 2008, we expect that competition from branded HFA MDIs will increase substantially. Furthermore, as a consequence of the ongoing commercialization of BROVANA, prescription levels for XOPENEX Inhalation Solution may be adversely affected to the extent that a significant number of physicians prescribe BROVANA, which could reduce the need for concomitant XOPENEX products. We may also face additional competition in the event of the commercial introduction of generic versions of our XOPENEX products.

To be successful with our XOPENEX products, we must demonstrate that the efficacy and safety features of these drugs outweigh the higher price as compared to generic albuterol and other competing products and that these attributes differentiate these products from other asthma and COPD treatments, including beta-agonist asthma and COPD treatments.

#### *BROVANA*

For COPD treatments solely, BROVANA faces competition from a variety of products. Competitive products include all products used in the treatment of COPD. COPD patients turn to numerous classes of drugs including anticholinergics, corticosteroids, mukolytics, long-acting beta-agonists, short-acting beta-agonists, theophyllines, and others. We estimate that our existing BROVANA prescriptions account for less than 1% of the total annual prescriptions currently being written in the United States for COPD pharmaceutical therapies, and less than 1% of beta-agonist COPD pharmaceutical therapies specifically. Even though BROVANA is a nebulized product, it also faces competition from long-acting beta-agonists and anticholinergics delivered by MDI and dry-powder inhaler. BROVANA also competes with combination therapy products used for COPD. In the fourth quarter of 2007, PERFOROMIST, a direct competitor with BROVANA, was launched, which we anticipate may impact adversely BROVANA's prescription levels. To be successful with BROVANA, we must demonstrate that patients with COPD will benefit by using BROVANA.

#### *OMNARIS AQ*

If and when it is commercialized, OMNARIS AQ, a corticosteroid nasal spray, will compete with perennial and seasonal allergic rhinitis treatments, and will face competition from oral antihistamines, intranasal antihistamines, intranasal decongestants, other intranasal corticosteroids, intranasal mast cell stabilizers, and antileukotrienes. To be successful with OMNARIS AQ, we must demonstrate that OMNARIS AQ's safety and efficacy features are superior to those of competing branded and generic products, some of which may be less expensive than OMNARIS AQ and may be available without a prescription. We may also face additional competition in the event of commercial introduction of a generic version of OMNARIS AQ.

For all of our products, we need to demonstrate to physicians, patients, and third-party payors that the cost of our product is reasonable and appropriate in light of its safety, efficacy, and health care benefits, each as compared to other competing products. In addition, if competitors introduce new products or develop new processes or new information about existing products, then our products, even

those protected by patents, may be replaced in the marketplace or we may be required to lower our prices.

***We may be unable to successfully commercialize products for which we receive approval from the FDA or similar foreign agencies.***

Commercialization of a product for which we have received an approval letter from the FDA or similar foreign agency could be delayed for a number of reasons, some of which are outside of our control, including delays in delivery of the product due to importation regulations and/or problems with our distribution channels or delays in the issuance of approvals from, or the completion of, required procedures by agencies other than the FDA, such as the United States Drug Enforcement Administration. In addition, commercialization of approved products may be delayed by our failure to timely finalize distribution arrangements, manufacturing processes and arrangements, produce sufficient inventory and/or properly prepare our sales force. If we are unable to successfully commercialize a product promptly after receipt of an approval letter, our business and financial position may be materially adversely affected due to reduced revenue from product sales during the period or periods that commercialization is delayed and the shortening of any lead time to market we may have had over our competitors. In addition, the exclusivity period, which is the time during which the FDA or similar foreign agency will prevent generic pharmaceutical companies from introducing a generic copy of the product, begins to run upon approval and, therefore, to the extent we are unable to successfully commercialize a product promptly after receipt of an approval letter, our long-term product sales and revenues could be adversely affected.

Even if the FDA or similar foreign agencies grant us regulatory approval of a product, if we fail to comply with the applicable regulatory requirements, we may be forced to suspend and/or cease commercialization of the product due to suspension or withdrawal of regulatory approvals, product recalls, seizures of products and/or operating restrictions and may be subject to fines and criminal prosecution. In any such event, our ability to successfully commercialize the product would be impaired and sales and revenues could be materially adversely affected.

***We may increase or decrease the size of our sales force in the future based on inaccurate assumptions. Future increases in our sales force will result in significant expenses. Such increases may be done in anticipation of approvals and/or expected sales growth that are not realized. If such approvals and/or growth are not realized, we will have incurred unnecessary expense and may also be forced to reduce our sales force. Future reductions in our sales force could prevent us from achieving anticipated revenues and attracting and retaining qualified sales personnel and could negatively impact our financial condition and results of operations.***

We sell our products, XOPENEX Inhalation Solution, XOPENEX HFA, BROVANA and LUNESTA, primarily through our direct sales force. During the fourth quarter of 2007, we reduced our direct sales force by approximately 300 positions. In February 2008, we announced that we intend to increase our sales force capacity by at least 200 sales professionals, in order to accommodate the commercialization of OMNARIS AQ and ALVESCO HFA. We expect that the costs of the anticipated increase in sales force capacity will offset the decrease in sales and marketing expenses we expected to realize as a result of the December 2007 sales force reduction. Any future expansion of the direct sales force will also require us to incur significant expenses. To the extent we expand our direct sales force in anticipation of receiving marketing approval for products under development, commercially introducing newly developed or acquired products and/or expected sales growth, we may again be forced to reduce our sales force if our expectations are not realized. In addition, our recent sales force reduction, and any future sales force reduction, may make it more difficult for us to attract the qualified sales people necessary to implement necessary sales force expansion, attract and retain qualified sales people necessary to maintain sales levels and/or to support potential sales growth and sales of additional products we may commercialize in the future.

***We sell our products primarily through a direct sales force, and if we are not successful in attracting and retaining qualified sales personnel, we may not be successful in commercializing our products.***

We have established a sales force to market our products. Our ability to realize significant revenues from direct marketing and sales activities depends on our ability to attract and retain qualified sales personnel. Competition for qualified sales personnel is intense. Our recent sales force reduction could harm our ability to attract and retain qualified sales personnel, which would prevent us from successfully expanding our marketing and direct sales force on a timely or cost effective basis and from successfully commercializing these newly acquired products. In addition, any failure to attract and retain qualified sales personnel in the future, could impair our ability to maintain sales levels, successfully commercialize new products and/or support expected future sales growth. Our recent sales force reduction, and any future sales force reduction, could also result in temporary lack of focus and reduced productivity among our sales personnel. If our sales organization does not devote the time and resources necessary to attain sales projections, we may not be able to achieve anticipated revenues and our financial condition and operating results could be harmed.

In February 2008, we announced that we intend to increase our sales force capacity by at least 200 sales professionals in order to accommodate the commercialization of OMNARIS AQ and ALVESCO HFA. We anticipate that this increase will be effectuated through an expansion of our direct sales force or through the services of a contract sales organization.

We may also need to enter into additional co-promotion, contract sales force or other such arrangements with third parties, for example, where our own direct sales force is not large enough or sufficiently well aligned to achieve maximum penetration in the market. We may not be successful in entering into any co-promotion, contract sales force or other such arrangements, and the terms of any co-promotion, contract sales force or other such arrangements may not be favorable to us.

***If we or our third-party manufacturers do not comply with current GMP regulations, then the FDA could refuse to approve marketing applications or force us to recall or withdraw our products.***

The FDA and other regulatory authorities require that our products be manufactured according to their GMP regulations. The failure by us, our collaborative development partners or our third-party manufacturers to comply with current GMP regulations could lead to delay in our development programs or refusal by the FDA or other regulatory authorities to approve marketing applications. Following marketing approval of a product, failure in either respect could also impede commercial introduction or on-going distribution of the product and/or be the basis for action by the FDA or other regulatory authorities to withdraw approvals previously granted, to recall products and for other regulatory action.

***We could be exposed to significant liability claims that could prevent or interfere with our product commercialization efforts.***

We may be subject to product liability claims that arise through testing, manufacturing, marketing, sale and use of pharmaceutical products. Product liability claims could distract our management and key personnel from our core business, require us to spend significant time and money in litigation or to pay significant damages, which could prevent or interfere with our product commercialization efforts and could adversely affect our business. Claims of this nature could also subject us to product recalls or adversely affect our reputation, which could damage our position in the market. Although we maintain product liability insurance coverage for both the clinical trials and products we commercialize, it is possible that we will not be able to obtain further product liability insurance on acceptable terms, if at all, and that our insurance coverage may not provide adequate coverage against all potential claims.

***Buying patterns of our wholesalers may vary from time to time, which could have a material impact on our financial condition, cash flows and results of operations.***

Sales of our products to wholesalers represent a substantial portion of our total sales. Buying patterns of our wholesalers may vary from time to time, in part as a result of pricing or seasonality. Wholesalers, or direct customers of wholesalers, may accumulate inventory in one quarter and limit product purchases in subsequent quarters, which could have a material impact on our financial condition, cash flows and results of operations.

We have entered into wholesaler fee-for-service agreements, or FFSAs, with our three largest customers. Under the FFSAs, we pay the wholesalers a fee to maintain certain minimum inventory levels that gradually decline over the next several quarters. We believe it is beneficial to enter into FFSAs to establish specified levels of product inventory to be maintained by our wholesalers and to obtain more precise information as to the level of our product inventory available throughout the product distribution channel. We record the cost associated with the FFSAs as revenue deductions. We cannot be certain that the FFSAs will be effective in limiting speculative purchasing activity, that there will not be a future drawdown of inventory as a result of declining minimum inventory requirements, or otherwise, or that the inventory level data provided through our FFSAs are accurate. If speculative purchasing does occur, if the wholesalers significantly decrease their inventory levels, or if inventory level data provided through FFSAs is inaccurate, our business, financial condition, cash flows and results of operations may also be adversely affected.

#### **Risks Related to the Regulatory Environment**

***If our products do not receive government approval, we will not be able to commercialize them.***

The FDA and similar foreign agencies must approve for commercialization any pharmaceutical products developed by us or our development partners. These agencies impose substantial requirements on drug manufacturing and marketing. Any unanticipated preclinical and clinical studies we are required to undertake could result in a significant increase in the cost of advancing our products to commercialization. In addition, failure by us or our collaborative development partners to obtain regulatory approval on a timely basis, or at all, or the attempt by us or our collaborative development partners to receive regulatory approval to achieve labeling objectives, could prevent or adversely affect the timing of commercial introduction of, or our ability to market and sell, our products.

***If we fail to successfully develop and receive regulatory approval for product candidates, we will be unable to commercialize the product candidates and future sales and earnings growth will be substantially hampered.***

Our ability to maintain profitability will depend in large part on successful development and commercialization of additional products. Most of our product candidates are in the early stages of development. We cannot be assured that we will be able to develop or acquire and commercially introduce new products in a timely manner or that new products, if developed or acquired, will be approved for the indications and/or with the labeling we expect, or that they will achieve market acceptance. Before we commercialize any other product candidate in the United States, we will need to successfully develop the product candidate by completing successful clinical trials, submitting an NDA for the product candidate that is accepted for filing by the FDA and receiving FDA approval to market the candidate. We must comply with similar requirements in foreign jurisdictions before commercializing any products in the jurisdiction. If we fail to successfully develop a product candidate and/or the FDA or similar foreign agency delays or denies approval of any NDA, or foreign equivalent, that we have submitted or submit in the future, then commercialization of our products under development may be delayed or terminated, which could have a material adverse effect on our business.

A number of problems may arise during the development of our product candidates, including the following:

- results of clinical trials may not be consistent with preclinical study results;
- results from later phases of clinical trials may not be consistent with results from earlier phases;
- results from clinical trials may not demonstrate that the product candidate is safe and efficacious;
- we may not receive regulatory approval for our product candidates;
- the product candidate may not offer therapeutic or other improvements over comparable drugs;
- we may elect not to continue funding the development of our product candidates; or
- funds may not be available to develop all of our product candidates.

Even if the FDA or similar foreign agencies grant us regulatory approval of a product, the approval may take longer than we anticipate and may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for costly post-marketing follow-up studies. Moreover, if we fail to comply with applicable regulatory requirements, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In addition, our growth is dependent on our continued ability to penetrate new markets where we have limited experience and competition is intense. We cannot be certain that the markets we serve will grow in the future, that our existing and new products will meet the requirements of these markets, that our products will achieve customer acceptance in these markets, that competitors or regulators will not force prices to an unacceptably low level or take market share from us, or that we can achieve or maintain profits in these markets.

***Our sales depend on payment and reimbursement from third-party payors, and a reduction in payment rate or reimbursement could result in decreased use or sales of our products.***

Sales of our products are dependent, in part, on the availability of reimbursement from third-party payors such as Federal and state government agencies under programs such as Medicare and Medicaid, and private insurance plans. Third-party payors continually attempt to contain or reduce the cost of health care by challenging the prices charged for medical products and services. We may not be able to sell our products profitably if reimbursement is unavailable or coverage is limited in scope or amount.

There have been, there are, and we expect there will continue to be, state and Federal legislative and/or administrative proposals that could limit the amount that state or Federal governments will pay to reimburse the cost of pharmaceutical products. Legislative or administrative acts that reduce reimbursement for our products could adversely affect our business. In addition, private insurers, such as managed care organizations, may adopt their own coverage restrictions or demand price concessions in response to legislation or administrative action. Reduction in reimbursement for our products could have a material adverse effect on our results of operations. Also, the increasing emphasis on managed care in the United States may put increasing pressure on the price and usage of our products, which may adversely affect product sales. Further, when a new drug product is approved, governmental and/or private reimbursement for that product is uncertain, as is the amount for which that product will be reimbursed and the extent of coverage for the product. We cannot predict availability or amount of reimbursement for our approved products or product candidates and current reimbursement policies for marketed products may change at any time.

The MMA established a prescription drug benefit beginning in 2006 for all Medicare beneficiaries. We do not know the extent to which our products will continue to be included in the Medicare



prescription drug benefit, and we may be required to provide significant discounts or rebates to drug plans participating in the Medicare drug benefit. Moreover, Congress may enact legislation that permits the Federal government to directly negotiate price and demand discounts on pharmaceutical products that may implicitly create price controls on prescription drugs. In addition, Managed Care Organizations, or MCOs, Health Maintenance Organizations, or HMOs, Preferred Provider Organizations, or PPOs, health care institutions and other government agencies continue to seek price discounts. MCOs, HMOs, PPOs and private health plans administer the Medicare drug benefit, leading to managed care and private health plans influencing prescription decisions for a larger segment of the population. In addition, certain states have proposed, and certain other states have adopted, various programs to control prices for their seniors' and low-income drug programs, including price or patient reimbursement constraints, restrictions on access to certain products, importation from other countries, such as Canada, and bulk purchasing of drugs.

In May 2007, CMS announced, that based on its interpretation of the statutory language of the MMA, it was required to discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and generic albuterol, which had been in place since January 2005, and instead calculate the reimbursement for XOPENEX Inhalation Solution and generic albuterol based on the blended weighted ASP for the two products. This new reimbursement became effective on July 1, 2007. Using a blended weighted ASP for XOPENEX Inhalation Solution results in reimbursement for the product that is considerably lower than the published selling price for the product in the wholesaler distribution channel. The new reimbursement rate is subject to change quarterly based upon the respective contribution of commercial sales of XOPENEX Inhalation Solution and generic albuterol to the quarterly blended weighted ASP calculation. This quarterly ASP calculation is mandated by the MMA. Revenues from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of this change.

The bundling action also resulted in an unintended increase in Medicare Part B reimbursement for generic albuterol, significantly higher than the product's average selling price (as publicly reported by the Medicare Part B program), creating the potential for inappropriate reimbursement incentives to influence the dispensing decisions of providers. On December 29, 2007, President Bush signed into law legislation, the effect of which mandates that XOPENEX Inhalation Solution and generic albuterol be reimbursed at the lower of their stand-alone weighted ASP and the blended weighted ASP for XOPENEX Inhalation Solution and generic albuterol. The effect of this legislation is that XOPENEX Inhalation Solution will continue to be reimbursed at the blended rate and generic albuterol will be reimbursed at its stand-alone weighted ASP. The legislation goes into effect on April 1, 2008.

We estimate that as much as 20% of our XOPENEX Inhalation Solution units sold are subject to reimbursement under Medicare Part B. We have been actively contracting with home health care and retail pharmacy providers in an effort to ensure the continued availability of XOPENEX Inhalation Solution to Medicare Part B beneficiaries with reversible obstructive airway disease. If the contracting strategy for XOPENEX Inhalation Solution is not successful in maintaining as much of the current unit sales levels for the product in Medicare as commercially possible, if the blended Medicare Part B reimbursement rate for XOPENEX Inhalation Solution and generic albuterol falls to an amount where it is no longer financially feasible to market XOPENEX Inhalation Solution to Medicare Part B participants and/or if the DME-PSCs, the entities responsible for overseeing the Medicare Part B prescription drug benefit for respiratory products, impose restrictive coverage policies on XOPENEX Inhalation Solution, revenue from sales of XOPENEX Inhalation Solution will be adversely affected and our financial condition and results from operations will be impaired.

On June 13, 2007, the DME-PSCs published an article detailing the coverage criteria for BROVANA. Unless otherwise modified by the DME-PSCs, the coverage criteria established for BROVANA in this article will remain in effect under the product-specific billing code that was awarded for the product. We have initiated a contracting strategy with retail and home health care pharmacy

providers for BROVANA that is intended to ensure the availability of the product for Medicare patients. If the contracting strategy for BROVANA is not successful or if the coverage policies established by the DME-PSCs for the product are viewed by physicians and providers as too restrictive, revenue growth from sales of BROVANA in the Medicare market will be materially adversely affected.

As we enter into agreements to license our products for commercialization outside of the United States, we may be subject to pricing decisions made by regulatory bodies and private insurers around the world. Such pricing decisions may affect royalty rates and payments made to us under those agreements, or decisions whether or not to commercialize our products in the applicable jurisdiction. Efforts to obtain pricing decisions are often the responsibility of the third party licensee and we cannot predict the success of any third party in obtaining desirable pricing, or how the actions of such third party or any regulatory body or private insurer will affect the ultimate commercial benefits of those transactions.

If reimbursement for our marketed products changes adversely or if we fail to obtain adequate reimbursement for our other current or future products, health care providers may limit how much or under what circumstances they will prescribe or administer them, which could reduce use of our products or cause us to reduce the price of our products.

*We will spend considerable time and money complying with Federal, state and foreign laws and regulations and, if we are unable to fully comply with such laws and regulations, we could face substantial penalties.*

We are subject to extensive regulation by Federal and state governments. The laws that directly or indirectly affect our business include, but are not limited to, the following:

- Federal Medicare and Medicaid Anti-Kickback laws, which prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce either referral of an individual, or furnishing or arranging for a good or service, for which payment may be made under Federal health care programs such as the Medicare and Medicaid programs;
- other Medicare and Medicaid laws and regulations that establish requirements for coverage and payment for our products, including the amount of such payments;
- the Federal False Claims Act, which imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government;
- the Federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any health care benefit program, including private payors and, further, requires us to comply with standards regarding privacy and security of individually identifiable health information and conduct certain electronic transactions using standardized code sets;
- the Federal False Statements Statute, which prohibits knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for health care benefits, items or services;
- the Federal Food, Drug and Cosmetic Act, which regulates manufacturing, labeling, marketing, distribution and sale of prescription drugs and medical devices;
- the Controlled Substances Act, which regulates handling of controlled substances such as LUNESTA;
- the Prescription Drug User Fee Act, which governs the filing of applications for marketing approval of new prescription drug products;

- the Food and Drug Administration Amendments Act of 2007;
- the Deficit Reduction Act of 2005;
- state and foreign law equivalents of the foregoing; and
- state food and drug laws, pharmacy acts and state pharmacy board regulations, which govern the sale, distribution, use, administration and prescribing of prescription drugs.

If our past or present operations are found to be in violation of any of the laws described above or other governmental regulations to which we or our customers are subject, we may be subject to the applicable penalty associated with the violation, including civil and criminal penalties, damages, fines, exclusion from Medicare and Medicaid programs and curtailment or restructuring of our operations. Similarly, if our customers are found non-compliant with applicable laws, they may be subject to sanctions, which could also have a negative impact on us. In addition, if we are required to obtain permits or licenses under these laws that we do not already possess, we may become subject to substantial additional regulation or incur significant expense. Any penalties, damages, fines, exclusion from Medicare and Medicaid programs or curtailment or restructuring of our operations would adversely affect our ability to operate our business and our financial results. The risk of our being found in violation of these laws is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts and their provisions are open to a variety of interpretations. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses, divert our management's attention from operating our business and damage our reputation.

Federal and state government agencies also continue to promote efforts to reduce health care costs, including those associated with the Medicare and Medicaid programs. These efforts may include supplemental rebates and restrictions on the amounts that agencies will reimburse for the use of products. In addition, both the Federal and state governments have initiated investigations and lawsuits concerning the Medicaid price reporting practices of many pharmaceutical companies to ensure compliance with the Medicaid rebate program. For example, in April 2007, we were sued by the County of Orange, New York in the Southern District of New York, along with over 70 other pharmaceutical companies, for allegedly inflating published average wholesale prices allegedly resulting in the overpayments by the state of New York's Medicaid program. This suit has been transferred by the Judicial Panel on Multidistrict Litigation to the District of Massachusetts, where the case is now pending as part of MDL 1456 (in re Pharmaceutical Industry Average Wholesale Price Litigation) and our obligation to answer the Complaint has been stayed pending the Court's decisions in related actions brought by other New York Counties against other defendants. We could be subject to damages and penalties as a consequence of this lawsuit, if we are found liable.

***The approval of sale of certain medications without a prescription may adversely affect our business.***

In May 2001, an advisory panel to the FDA recommended that the FDA allow certain popular allergy medications to be sold without a prescription. In November 2002, the FDA approved CLARITIN, an allergy medication, to be sold without a prescription. In November 2007, the FDA also approved ZYRTEC, another allergy medication, to be sold without a prescription. In the future, the FDA may allow sale of additional allergy medications without a prescription. The sale of CLARITIN, ZYRTEC and/or, if allowed, the sale of other allergy medications without a prescription, may have a material adverse effect on our business because the market for prescription drugs, including CLARINEX, ALLEGRA, and XYZAL/XUSAL for which we receive royalties on sales, has been and may continue to be, adversely affected.

*We recently determined that PHS discounts were provided to non-PHS covered entities. This circumstance creates uncertainty as to whether a new best price was set in prior periods. If a new best price was set, additional Medicaid rebates will be required to be paid. In addition, we may face an increased risk of investigation or litigation concerning our Medicaid price reporting or other price reporting obligations.*

Under the Medicaid rebate program, we are obligated to pay a rebate to each participating State Medicaid program for each unit of product reimbursed by Medicaid. The amount of the rebate for each product is set by law as the greater of (a) 15.1% of AMP or (b) the difference between AMP and the Medicaid best price, which is the lowest price available from us to any customer not excluded by law from that determination. The rules related to determining AMP and best price are complicated. We compute best price and the required rebate payments each quarter based on our knowledge of the statutory requirements, the current CMS guidance and our understanding of which customers are exempt from the best price calculation.

In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. As a follow up to this disclosure to CMS, our management, with the oversight of our Audit Committee, is reviewing our government pricing activities affected by the material weakness on our internal controls related to these potential errors. We restated our financial statements for the years ended December 31, 2006 and 2005 and the unaudited quarterly information in Note T in our consolidated financial statements for the fiscal quarters ended March 31, June 30 and September 30, 2007 and 2006 to reduce the amount of product revenue earned during such periods. The amounts by which we have reduced revenues for contingent rebates were based on management's best estimates and assumptions made prior to any concurrence by CMS. These amounts may change as a result of future communications with CMS, and we cannot be certain that we have not overestimated the amount of additional rebates we may be required to pay, that the amount of any additional rebate payments or other payments we may owe will not exceed our current estimates, or that we will not be subject to fines, penalties or interest.

Both the federal government and state governments have initiated investigations and lawsuits concerning the Medicaid price reporting practices of many pharmaceutical companies to ensure compliance with the Medicaid rebate program. As a result of the errors that we identified in our calculation of Medicaid rebate reserve amounts, we may face an increased risk of a government investigation or lawsuits concerning our Medicaid or other price reporting. If any such investigation or lawsuit is initiated, we may be required to pay additional rebates or other amounts related to sales made in prior periods, and we may be subject to fines, penalties or interest. In addition, an investigation or lawsuit concerning our Medicaid price reporting could be costly, could divert the attention of our management from our core business and could damage our reputation.

*If our drugs are not included on state Preferred Drug Lists, use of our drugs may be negatively affected.*

Several state Medicaid programs have implemented PDLs and more states may adopt this practice. Products placed on a state Medicaid program's PDL are not subject to restrictions on their utilization by Medicaid patients, such as the need to obtain authorization prior to prescribing. If our drugs are not included on Medicaid PDLs, use of our drugs in the Medicaid program may be adversely affected. In some States that have adopted PDLs, we have been, and may continue to be, required to provide substantial supplemental rebates to state Medicaid authorities in order for our drugs to be included on the PDL.

## **Risks Related to Our Intellectual Property**

*If we fail to adequately protect or enforce our intellectual property rights, then we could lose revenue under our licensing agreements or lose sales to generic copies of our products.*

Our success depends in large part on our ability, and the ability of our collaboration partners, to obtain, maintain and enforce patents, and protect trade secrets. Our ability to commercialize any drug successfully will largely depend upon our ability to obtain and maintain patents of sufficient scope to prevent third parties from developing substantially equivalent products. In the absence of patent and trade secret protection, competitors may adversely affect our business by independently developing and marketing substantially equivalent products. It is also possible that we could incur substantial costs if we are required to initiate litigation against others to protect or enforce our intellectual property rights.

We have filed patent applications covering composition of, methods of making, and/or methods of using, our drugs and drug candidates. Our revenues under collaboration agreements with pharmaceutical companies depend in part on the existence and scope of issued patents. We may not be issued patents based on patent applications already filed or that we file in the future and if patents are issued, they may be insufficient in scope to cover the products licensed under these collaboration agreements. Generally, we do not receive royalty revenue from sales of products licensed under collaboration agreements in countries where we do not have a patent for such products. The issuance of a patent in one country does not ensure the issuance of a patent in any other country. Furthermore, the patent position of companies in the pharmaceutical industry generally involves complex legal and factual questions, and has been and remains the subject of much litigation. Legal standards relating to scope and validity of patent claims are evolving. Any patents we have obtained, or obtain in the future, may be challenged, invalidated or circumvented. Moreover, the United States Patent and Trademark Office may commence interference proceedings involving our patents or patent applications. Any challenge to, or invalidation or circumvention of, our patents or patent applications would be costly, would require significant time and attention of our management and could have a material adverse effect on our business. In addition, if we are not successful in enforcing our patents, we will not be able to prevent others from introducing generic versions of our products.

*A number of our products and products for which we receive royalties are the subject of patent invalidation claims.*

XOPENEX Inhalation Solution is currently the subject of patent infringement litigation. The FDA has received ANDAs from Breath, Dey, L.P., Watson and Barr seeking marketing approval for generic versions of our XOPENEX Inhalation Solution products. These submissions include Paragraph IV certifications alleging that our patents listed in the Orange Book for XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the submitter's proposed product. We have commenced patent infringement litigation against Breath, Dey, L.P., and Barr, but we have decided not to commence litigation against Watson at this time as its Paragraph IV certification is limited to a patent that expires in 2021. The filing of a lawsuit for patent infringement under the Hatch-Waxman Act results in an automatic 30-month stay of the FDA's authority to grant marketing approval to these companies. The 30-month stay against Breath's ANDA is scheduled to expire for our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution on or about March 7, 2008. In December 2007, the FDA granted tentative approval to Breath's ANDA for all three dosages. A non-jury trial in our litigation against Breath is scheduled to begin on July 14, 2008 in the United States District Court for the District of Delaware, C.A. No. 06-113. No trial date has been set in our patent infringement litigation against Dey, L.P. or Barr.

Upon expiration of that 30-month stay, the FDA could grant final approval and Breath could then commence an "at risk" distribution of its generic levalbuterol product for those dosages notwithstanding our patents and notwithstanding that the court's decision as to the merits of the

litigation will not have been rendered, unless we were able to obtain an injunction prohibiting such distribution. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stays against Dey, L.P. and Barr expire on or about July 9, 2008 and November 30, 2009, respectively. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution product prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate and we would have to revise such guidance.

Certain of Schering-Plough's CLARINEX products for which we receive sales royalties are currently the subject of patent infringement litigation and in 2007, the FDA received a number of ANDAs relating to CLARINEX. These ANDA submissions include Paragraph IV certifications alleging that our patents, which Schering Plough (as licensee of such patents) listed in the Orange Book for these products, are invalid, unenforceable or not infringed by the submitter's proposed product. We and the University of Massachusetts, co-owners of certain patents listed in the Orange Book, filed civil actions against these parties for patent infringement. We believe that all of these ANDAs are subject to a statutory stay of approval until June 21, 2009 based on previous litigation commenced by Schering-Plough against these parties in separate civil actions involving another patent.

In addition, a number of our foreign patents that we have out-licensed to Schering-Plough, sanofi-aventis and UCB in connection with the sale of CLARINEX, ALLEGRA and XYZAL/XUSAL, respectively, are subject to patent invalidity claims. If patent-based exclusivity is lost for one or more of these products in any foreign jurisdiction, our rights to receive royalty revenue with respect to such product in the relevant jurisdiction will terminate, which may have a material adverse effect on our business, financial condition and results of operations. Should the courts uphold our foreign patents, companies seeking to market generic versions of our drugs and the drugs of our licensees should be deterred from market entry until the expiration of the applicable patent(s).

Patent litigation involves complex legal and factual questions. We can provide no assurance concerning the outcome or the duration of any patent related lawsuits. If we, or third parties from whom we receive royalties, are not successful in enforcing our respective patents, the companies seeking to market generic versions of our drugs and the drugs of our licensees will not be excluded, for the full term of our patents, from marketing their generic versions of our products or third party products for which we have licensed rights to our patents. Introduction of generic copies of any of our products or third party products for which we have licensed rights to our patents before the expiration of our patents would have a material adverse effect on our business.

Additionally, the costs to us of these proceedings, even if resolved in our favor, could be substantial. Such litigation could also substantially divert the attention of our management and other key personnel from our core business and our resources in general. Uncertainties resulting from the initiation and continuation of this and any other litigation proceedings could harm our ability to compete in the marketplace.

***If we face a claim of intellectual property infringement by a third party, then we could be liable for significant damages or be prevented from commercializing our products.***

Our success depends in part on our ability to operate without infringing upon proprietary rights of others, including patent and trademark rights. Third parties, typically drug companies, hold patents or patent applications covering compositions, methods of making and uses, covering the composition of

matter for some of the drug candidates for which we have patents or patent applications. Third parties also hold patents relating to drug delivery technology that may be necessary for development or commercialization of some of our drug candidates. In each of these cases, unless we have or obtain a license agreement, we generally may not commercialize the drug candidates until these third-party patents expire or are declared invalid or unenforceable by the courts. Licenses may not be available to us on acceptable terms, if at all.

Others may file suit against us alleging that our products or product candidates infringe patents they hold. Even if resolved in our favor, any patent infringement litigation would be costly, would require significant time and attention of our management, could prevent us from commercializing our products for a period of time and could require us to pay significant damages and could have a material adverse effect on our business. If the matter is not resolved in our favor, we could be required to pay significant damages and/or be prevented from commercializing our product and our business could be materially adversely affected. In April 2007, we were served with a Complaint filed by Dey, alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single U.S. patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaim to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. Under the current trial scheduling order, trial will begin no earlier than January 12, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

If any of our trademarks or the trademarks we license from our third party collaborators, or our use of any of these trademarks in connection with products we commercialize, is challenged, we or our third party collaborators may be forced to rename the affected product or product candidate, which could be costly and time consuming, and would result in the loss of any brand equity associated with the product name.

#### **Risks Related to Our Dependence on Third Parties**

*If any third-party collaborator is not successful in development or commercialization of our products and product candidates, we may not realize the potential commercial benefits of the arrangement and our results of operations could be adversely affected.*

We have entered into a collaboration agreement with 3M for the manufacturing of XOPENEX HFA. Under this agreement, 3M is responsible for manufacturing an MDI formulation of XOPENEX. We commercially introduced XOPENEX HFA in December 2005. We have also entered into agreements with Eisai and GSK for development and commercialization of our eszopiclone product, marketed as LUNESTA in the U.S. Under the Eisai agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on regulatory approval, commercialization of the product in Japan. Under the GSK agreement, GSK is responsible for the development and commercialization of the product for all markets worldwide, excluding the United States, Canada, Mexico and Japan. In addition, we have also recently entered into a license agreement with Bial for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound, BIA 2-093, which we subsequently renamed SEP-0002093. Under this agreement, Bial is responsible for certain development activities and prosecuting all patents and patent applications it licensed to us. We have also recently entered into a distribution and development agreement with Nycomed for the development, commercialization and distribution in the United States, its territories and possessions of Nycomed's compound ciclesonide, and certain products incorporating such compound, including ALVESCO HFA and OMNARIS AQ. Under this agreement, Nycomed is responsible for prosecuting all patents and patent applications with respect to these products.

If 3M, Eisai, GSK, Bial, Nycomed or any future development or commercialization collaborator does not devote sufficient time and resources to its collaboration arrangement with us, breaches or terminates its agreement with us, fails to perform its obligations to us in a timely manner, is unsuccessful in its development and/or commercialization efforts, or is unsuccessful in obtaining, maintaining or enforcing patents, and/or protecting trade secrets we license from such collaborator, we may not realize the potential commercial benefits of the arrangement and our results of operations may be adversely affected. In addition, if regulatory approval or commercialization of any product candidate under development by or in collaboration with a partner is delayed or limited, we may not realize, or may be delayed in realizing, the potential commercial benefits of the arrangement.

*The royalties and other payments we receive under licensing arrangements could be delayed, reduced or terminated if our licensing partners terminate, or fail to perform their obligations under, their agreements with us, or if our licensing partners are unsuccessful in their sales efforts.*

We have entered into licensing arrangements pursuant to which we license patents to pharmaceutical companies and our revenues under these licensing arrangements consist primarily of milestone payments, royalties on sales of products and supply payments. Payments and royalties under these arrangements depend in large part on the efforts of our licensing partners in countries where we hold patents, including development and sales efforts and enforcement of patents, which we cannot control. If any of our licensing partners do not devote sufficient time and resources to its licensing arrangement with us or focuses its efforts in countries where we do not hold patents, we may not realize the potential commercial benefits of the arrangement, our revenues under these arrangements may be less than anticipated and our results of operations may be adversely affected. If any of our licensing partners was to breach or terminate its agreement with us or fail to perform its obligations to us in a timely manner, the royalties and other payments we receive under the licensing agreement could decrease or cease. If we are unable or fail to perform, or breach in our performance of, our obligations under a licensing agreement, the royalties and other payments and benefits to which we are otherwise entitled under the agreement could be reduced or eliminated. Any delay or termination of this type could have a material adverse effect on our financial condition and results of operations because we may lose technology rights and milestone or royalty payments from licensing partners and/or revenues from product sales, if any, could be delayed, reduced or terminated.

*We rely on third-party manufacturers, and this reliance could adversely affect our ability to meet our customers' demands.*

We currently operate a manufacturing plant that we believe can meet our commercial requirements of the active pharmaceutical ingredient for XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA, partially fulfill our commercial requirements of the active pharmaceutical ingredient for LUNESTA, and support production of our product candidates in amounts needed for our clinical trials. We do not, however, have the capability to manufacture at our manufacturing facility all of our requirements for the active ingredients of our currently approved products, and we have no facilities for manufacturing pharmaceutical dosage forms or finished drug products. Developing and obtaining this capability would be time consuming and expensive. Unless and until we develop this capability, we will rely substantially, and in some cases, entirely, on third-party manufacturers. Catalent and Holopack are currently our only finished goods manufacturers of our XOPENEX Inhalation Solution and Catalent is currently the sole finished goods manufacturer of BROVANA. Patheon Inc., or Patheon, is the sole manufacturer of LUNESTA, and 3M is the sole manufacturer and supplier of XOPENEX HFA. Certain components of XOPENEX HFA are available from only a single source. If Catalent, Holopack, Patheon, 3M, or any of our sole-source component suppliers experiences delays or difficulties in producing, packaging or delivering XOPENEX Inhalation Solution, XOPENEX HFA or its components, BROVANA or LUNESTA, as the case may be, we could be unable to meet our customers' demands for such products, which could lead to lost sales, customer dissatisfaction and



damage to our reputation. Moreover, if we experience delays or difficulties meeting our supply obligations to GSK and Eisai as a result of our third party suppliers and manufacturers not meeting our demands, or for any other reason, we may not realize the potential commercial benefits of our supply and/or licensing arrangements with these parties and our results of operations may be adversely affected. If we are required to change manufacturers, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines, including FDA guidelines. The delays associated with the verification of a new manufacturer for XOPENEX Inhalation Solution, XOPENEX HFA or its components, BROVANA or LUNESTA could adversely affect our ability to produce such products in a timely manner or within budget.

Pursuant to our distribution, development and commercialization agreement with Nycomed, Nycomed will be responsible for exclusively manufacturing and supplying us with our requirements of ALVESCO HFA and OMNARIS AQ and OMNARIS HFA. Furthermore, in the event that we develop and commercialize any additional products containing the compound ciclesonide, Nycomed, upon request, will be our exclusive supplier of such additional products. If Nycomed experiences delays or difficulties in producing, packaging or delivering ALVESCO HFA, OMNARIS AQ, OMNARIS HFA, or other products containing the compound ciclesonide, we could be unable to meet our customers' demands for such products, which could lead to lost sales, customer dissatisfaction and damage to our reputation.

We license certain proprietary technology required to manufacture our XOPENEX HFA from 3M. If 3M is unable or unwilling to fulfill its obligations to us under our agreement, we may be unable to manufacture XOPENEX HFA on terms that are acceptable to us, if at all. Our other current contract manufacturers, as well as any future contract manufacturers, may also independently own technology related to manufacturing of our products. If so, we would be heavily dependent on such manufacturer and such manufacturer could require us to obtain a license in order to have another party manufacture our products.

#### **Risks Related to Growth of Our Business**

*If we fail to acquire and develop additional product candidates or approved products, our ability to grow will be impaired.*

We are currently commercializing four products, recently acquired from Nycomed the exclusive U.S. distribution rights to two FDA-approved products and the development rights to one late-stage product candidate, and recently licensed one late-stage product candidate from Bial. However, all of our other product candidates are in the early stages of development. In order to increase the likelihood that we will be able to successfully develop and/or commercialize additional drugs, we intend to acquire and develop additional product candidates and/or approved products. The success of this growth strategy depends upon our ability to correctly establish criteria for such acquisitions and successfully identify, select and acquire product candidates and/or products that meet such criteria. We will be required to integrate any acquired product candidates, including BIA 2-093, which we now refer to as SEP-0002093, and product candidates we are developing pursuant to our agreement with Nycomed, into our research and development operations and any acquired products, including ALVESCO HFA and OMNARIS AQ into our sales and marketing operations. Managing the development and/or commercialization of a new product involves numerous other financial and operational risks, including difficulties allocating resources between existing and acquired assets and attracting and retaining qualified employees to develop and/or sell the product.

Any product candidate we acquire may require additional research and development efforts prior to commercial sale, including extensive preclinical and/or clinical testing and approval by the FDA and corresponding foreign regulatory authorities. All product candidates are prone to the risks of failure

inherent in pharmaceutical product development, including the possibility that the product candidate will not be safe and effective or approved by regulatory authorities.

In addition, we cannot be assured that any products that we develop or acquire will be:

- manufactured or produced economically;
- successfully commercialized or reimbursed at rates sufficient for us to achieve or maintain profitability with respect to such products;
- complementary to our existing product portfolio; or
- widely accepted in the marketplace.

Proposing, negotiating and implementing an economically viable acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the acquisition of product candidates and approved products. We may not be able to acquire the rights to additional product candidates and approved products on terms that we find acceptable, or at all.

*We may undertake strategic acquisitions in the future and any difficulties from integrating such acquisitions could adversely affect our stock price, business operations, financial condition or results from operations.*

We may acquire additional businesses, products or product candidates that complement or augment our existing business. We have limited acquisition experience and may not be able to integrate any acquired business, product or product candidate successfully or operate any acquired business profitably. Integrating any newly acquired business, product or product candidate could be expensive and time-consuming. Integration efforts often place a significant strain on managerial, operational and financial resources and could prove to be more difficult or expensive than we predict. The diversion of our management's attention and any delay or difficulties encountered in connection with any future acquisitions we may consummate could result in the disruption of our on going business or inconsistencies in standards, controls, procedures and policies that could adversely affect our ability to maintain relationships with customers, suppliers, collaborators, employees and others with whom we have business dealings. Moreover, we may need to raise additional funds through public or private debt or equity financing to acquire any businesses, products or product candidates, which may result in dilution for stockholders or the incurrence of indebtedness.

As part of our efforts to acquire businesses, products or product candidates or to enter into other significant transactions, we conduct business, legal and financial due diligence with the goal of identifying and evaluating material risks involved in the transaction. Despite our efforts, we ultimately may be unsuccessful in ascertaining or evaluating all such risks and, as a result, might not realize the intended advantages of the transaction. If we fail to realize the expected benefits from acquisitions we have consummated or may consummate in the future, whether as a result of unidentified risks, integration difficulties, regulatory setbacks or other events, our business, results of operations and financial condition could be adversely affected. We will also need to make certain assumptions regarding acquired product candidates, including, among other things, development costs, the likelihood of receiving regulatory approval and the market for such product candidates. Our assumptions may prove to be incorrect, which could cause us to fail to realize the anticipated benefits of these transactions.

In addition, we will likely experience significant charges to earnings in connection with our efforts, if any, to consummate acquisitions. For transactions that are ultimately not consummated, these charges may include fees and expenses for investment bankers, attorneys, accountants and other advisers in connection with our efforts. Even if our efforts are successful, we may incur as part of a transaction substantial charges for closure costs associated with elimination of duplicate operations and facilities

and acquired in-process research and development charges. In either case, the incurrence of these charges could adversely affect our results of operations for particular quarterly or annual periods.

*Development and commercialization of our product candidates could be delayed or terminated if we are unable to enter into collaboration agreements in the future or if any future collaboration agreement is subject to lengthy government review.*

Development and commercialization of some of our product candidates may depend on our ability to enter into additional collaboration agreements with pharmaceutical companies to fund all or part of the costs of development and commercialization of these product candidates. We may not be able to enter into collaboration agreements and the terms of the collaboration agreements, if any, may not be favorable to us. Inability to enter into collaboration agreements could delay or preclude development, manufacture and/or marketing of some of our drugs and could have a material adverse effect on our financial condition and results of operations because:

- we may be required to expend additional funds to advance the drugs to commercialization;
- revenue from product sales could be delayed; or
- we may elect not to commercialize the drugs.

We are required to file a notice under the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, or the HSR Act, for certain agreements containing exclusive license grants and to delay the effectiveness of any such exclusive license until expiration or earlier termination of the notice and waiting period under the HSR Act. If expiration or termination of the notice and waiting period under the HSR Act is delayed because of lengthy government review, or if the Federal Trade Commission or Department of Justice successfully challenges such a license, development and commercialization could be delayed or precluded and our business could be adversely affected.

#### **Item 1B. Unresolved Staff Comments.**

None.

#### **Item 2. Properties.**

Our main facility at 84 Waterford Drive, Marlborough, Massachusetts, consists of approximately 58 acres and a 192,600 square foot research and development and corporate office building, which we purchased in November 2002. In November 2007, we entered into an agreement with a commercial builder for the construction of a 143,000 square foot building to be used by us as additional office space. We anticipate that construction of this building will be completed in the first quarter of 2009.

We lease space in two additional facilities in Marlborough, Massachusetts. We lease 57,477 square feet of office and laboratory space at 33 Locke Drive. This is comprised of two leases that expire on February 28, 2009 and June 30, 2012. We lease 68,815 square feet of office space at 111 Locke Drive under a lease that will expire on June 30, 2012. The 111 Locke Drive facility serves as our regional sales office for the northeast region, as our sales training facility and additional office space.

During 2004, we entered into four leases for office space that serve as regional sales offices. These offices are located in Irvine, California; Alpharetta, Georgia; Deerfield, Illinois, and Flower Mound, Texas. These leases expire on December 31, 2009, October 31, 2011, October 31, 2009 and June 30, 2011, respectively.

Our primary manufacturing location is a 50,000 square-foot fine chemical manufacturing facility located on a four-acre site in Windsor, Nova Scotia, which we acquired in March 1994. Production at the Nova Scotia facility began in February 1995.

### **Item 3. Legal Proceedings.**

#### ***Litigation Related to Generic Competition and Patent Infringement***

Patent litigation involves complex legal and factual questions. We can provide no assurance concerning the outcome or the duration of any patent related lawsuits. If we, or third parties from whom we receive royalties, are not successful in enforcing our respective patents, the companies seeking to market generic versions of our drugs and the drugs of our licensees will not be excluded, for the full term of the respective patents, from marketing their generic versions of our products or third party products for which we have licensed rights to our patents. Introduction of generic copies of any of our products or third party products for which we have licensed rights to our patents before the expiration of our patents would have a material adverse effect on our business, financial condition and results of operations.

#### **Levalbuterol Hydrochloride Inhalation Solution Abbreviated New Drug Applications**

In September 2005, we received notification that the FDA had received an ANDA from Breath seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Breath's submission includes a Paragraph IV certification alleging that our patents listed in the FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book," for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Breath is seeking approval. In October 2005, we filed a civil action against Breath for patent infringement and a non-jury trial is scheduled to begin on July 14, 2008 in the United States District Court for the District of Massachusetts, No. CV:06-10043.

In January 2006, we received notification that the FDA had received an ANDA from Dey, L.P., seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL XOPENEX Inhalation Solution. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. is seeking approval. In February 2006, we filed a civil action against Dey, L.P. for patent infringement and the case is pending in the United States District Court for the District of Delaware, C.A. No. 06-113.

In August 2006, we received notification that the FDA had received an ANDA from Dey, L.P. seeking approval of a generic version of our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. is seeking approval. In September 2006, we filed a civil action against Dey, L.P. for patent infringement in the United States District Court for the District of Delaware, C.A. No. 06-604. In September 2006, both civil actions we filed against Dey, L.P. were consolidated into a single suit. No trial date has been set.

In May 2007, we received notification that the FDA had received an ANDA from Barr seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Barr's submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Barr is seeking approval. In July 2007, we filed a civil action against Barr for patent infringement and the case is pending in the United States District Court for the District of Delaware, C.A. No. 07-438. No trial date has been set.

The filing of an action for patent infringement under the Hatch-Waxman Act invokes an automatic 30-month stay of the FDA's authority to grant final marketing approval to those companies that file an ANDA containing a Paragraph IV certification against one or more of our XOPENEX Inhalation

Solution patents. The first filer of an ANDA with a Paragraph IV certification is potentially entitled to a 180-day period of semi-exclusivity during which the FDA cannot approve subsequently filed ANDAs. The 180-day semi-exclusivity period would begin to run only upon first commercial marketing by the first filer. There are, however, also certain events that could cause the first filer to forfeit the 180-day semi-exclusivity period, which we refer to as a forfeiture event.

For our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL XOPENEX Inhalation Solution, we believe that Breath is the first filer and potentially entitled to 180-days of semi-exclusivity against subsequent ANDA filers for those three dosages. The 30-month stay against Breath's ANDA is scheduled to expire on or about March 7, 2008. In December 2007, the FDA granted tentative approval to Breath's ANDA for all three dosages. Upon expiration of that 30-month stay, the FDA could grant final approval and Breath could then commence an "at risk" distribution of its generic levalbuterol product for those dosages notwithstanding our patents and notwithstanding that the court's decision as to the merits of the litigation will not have been rendered, unless we were able to obtain an injunction prohibiting such distribution. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stays against Dey, L.P. and Barr expire on or about July 9, 2008 and November 30, 2009, respectively.

For our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate, we believe that Dey, L.P. is the first filer and potentially entitled to 180-days of semi-exclusivity for that concentration. The 30 month stay against Dey, L.P.'s ANDA for that concentration expires on or about February 14, 2009.

Although we could seek recovery of any damages sustained in connection with any activities conducted by a party that infringe a valid and enforceable claim in our patents, whether we are ultimately entitled to such damages would be determined by the court in connection with our ongoing legal proceedings with each party desiring to launch generic levalbuterol hydrochloride products. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution product prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate and we would have to revise such guidance.

#### **Desloratadine Abbreviated New Drug Applications**

In June 2007, we received notification that the FDA had received an ANDA from Glenmark Pharmaceuticals, Ltd. and Glenmark Pharmaceuticals, Inc., USA, which we refer to collectively as Glenmark, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Glenmark's submission includes a Paragraph IV certification alleging that our patents that Schering-Plough (as licensee of such patents) listed in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic version for which Glenmark is seeking approval. In July 2007, we and the University of Massachusetts, co-owners of certain patents listed in the Orange Book, filed a civil action in the United States District Court for the District of New Jersey against Glenmark for patent infringement, C.A. No. 07-3385.

In July 2007, we received notification that the FDA had received an ANDA from Sun Pharmaceutical Industries, Ltd., or Sun, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Sun's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable, or are not infringed by the generic version for which Sun is seeking approval. In

September 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Sun for patent infringement, C.A. No. 07-4213.

In August 2007, we received notification that the FDA had received an ANDA from Orchid Chemicals & Pharmaceuticals, Ltd., or Orchid, seeking approval of a generic version of Schering-Plough's 5 mg tablets, and 2.5 and 5 mg orally disintegrating tablets of CLARINEX. Orchid's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic version for which Orchid is seeking approval. In October 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Orchid for patent infringement, C.A. No. 07-4623.

In September 2007, we received notification that the FDA had received ANDAs from Mylan Pharmaceuticals, Inc., or Mylan, Lupin Limited, or Lupin, and Perrigo R & D Company, or Perrigo, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX, and from Dr. Reddy's Laboratories, or Dr. Reddy's, seeking approval of generic versions of Schering-Plough's (1) 5 mg tablets of CLARINEX, (2) 2.5 mg and 5 mg orally disintegrating tablets of CLARINEX, (3) 2.5/120 mg tablets of CLARINEX-D 12 hour desloratadine and pseudoephedrine, and (4) 5.0/240 mg tablets of CLARINEX-D 24 hour desleratodine and pseudoephedrine extended release tablets. The submissions by these parties include Paragraph IV certifications alleging that certain patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic versions for which these parties are seeking approval. In October 2007, we and the University of Massachusetts filed civil actions in the United States District Court for the District of New Jersey against Mylan, Lupin, Perrigo and Dr. Reddy's for patent infringement, C.A. No. 3:07-cv-05017, C.A. No. 3:07-cv-05265, C.A. No. 3:07-cv-05136 and C.A. No. 3:07-cv-05001, respectively.

In October 2007, we received notification that the FDA had received an ANDA from Anchen Pharmaceuticals, Inc., or Anchen, seeking approval of a generic version of Schering-Plough's 2.5/120 mg tablets of CLARINEX-D 12 hour desloratadine and pseudoephedrine extended release tablets. Anchen's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic version for which Anchen is seeking approval. In November 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Anchen for patent infringement, C.A. No. 07-cv-5737.

In September 2007, we received notification that the FDA had received an ANDA from Sandoz, Inc., or Sandoz, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Sandoz's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable, or are not infringed by the generic version for which Sandoz is seeking approval. In December 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Sandoz for patent infringement, C.A. No. 3:07-cv-04213.

In February 2008, we received notification that the FDA had received an ANDA from Belcher Pharmaceuticals, Inc., or Belcher, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Belcher's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable, or are not infringed by the generic version for which Belcher is seeking approval. In February 2008, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Belcher for patent infringement, C.A. No. 3:08-cv-00945.

We believe that all of these ANDAs are subject to a statutory stay of approval until June 21, 2009 based on previous litigation commenced by Schering-Plough against these parties in separate civil actions involving another patent.

#### **BROVANA Patent Infringement Claim**

In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey, alleging that manufacture and sale of BROVANA® (arformoterol tartrate) Inhalation Solution infringes or will induce infringement of a single U.S. patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaim to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. Under the current trial scheduling order, trial will begin no earlier than January 12, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

#### ***Stock Option Inquiry and Derivative Stockholder Complaints***

We announced in November 2007 that we had received notice from the SEC that the informal inquiry into our stock option grants and stock option granting practice had been completed and that no enforcement action was recommended.

From June to October 2006, six stockholder derivative complaints were commenced against us (as a nominal defendant) and certain of our current and former officers and directors. Three of these complaints were filed in the Superior Court, Middlesex County, Commonwealth of Massachusetts (later transferred to the Business Litigation Session of the Superior Court, Suffolk County, Commonwealth of Massachusetts) and three were filed in the United States District Court for the District of Massachusetts. All state court complaints were later consolidated into one state court action, and all Federal court complaints were consolidated into one Federal court action. It was alleged in both actions that the individual defendants breached their fiduciary duties and were unjustly enriched in connection with certain stock option grants; violations of Federal securities laws were alleged in the Federal action as well. The complaints sought monetary damages in unspecified amounts, equitable and injunctive relief, including disgorgement of profits obtained by certain defendants and other relief as determined by the court.

In October 2007, we reached a settlement with the parties to both the state and Federal action providing for the dismissal of both actions, subject to the approval of the court. The settlement resolves all claims and includes no finding of wrongdoing on the part of any of the defendants and no cash payment other than attorneys' fees. As part of the settlement, we implemented stock option grant and other procedures that reflect developing best practices. The settlement became final and effective in January 2008 upon final approval by the state court and entry of dismissal with prejudice by the Federal court.

#### ***Tecastemizole Class Action Complaints***

In June 2007, we filed in the United States District Court for the District of Massachusetts, or the Court, a Stipulation of Settlement regarding two securities class action lawsuits, or class actions, pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. The class actions, which were filed on behalf of certain purchasers of our equity and debt securities, or the plaintiffs, allege that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. The Stipulation of Settlement contains no admission of wrongdoing. Sepracor and the other defendants have always maintained and continue to believe that we did not

engage in any wrongdoing or otherwise commit any violation of Federal or state securities laws or other laws. However, given the potential cost and burden of continued litigation, we believe the settlement was in our best interests and the best interests of our stockholders. Under the terms of the Stipulation of Settlement, in June 2007 we paid into escrow \$52.5 million in settlement of the class actions and, in July 2007, received an \$18.5 million reimbursement from our insurance carriers. We recorded the litigation settlement expense of \$34.0 million, relating to this matter, during the quarter ended March 31, 2007. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow. Pursuant to the final judgment entered by the Court, the Court dismissed the class actions with prejudice, and the plaintiffs are deemed to have released all claims against us.

#### ***LUNESTA Trademark Claim***

In September 2006, Tharos Laboratories, Inc., or Tharos, filed suit against us in the United States District Court, District of Utah, Central Division, 2:06-cv-00757, alleging trademark infringement, dilution, unfair competition, false advertising and false designation of origin arising out of our use of our silk luna moth design in connection with LUNESTA. Tharos sought unspecified monetary damages and to enjoin our use of the silk luna moth design. In October 2007, we reached a final agreement with Tharos, and the case has been dismissed.

#### ***Other Legal Proceedings***

From time to time we are party to other legal proceedings in the course of our business. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

#### **Item 4. Submission of Matters to a Vote of Security Holders.**

No matters were submitted to a vote of our security holders, through solicitation of proxies or otherwise, during the last quarter of the year ended December 31, 2007.



## EXECUTIVE OFFICERS OF THE REGISTRANT

The following table sets forth the names, ages and positions of our current executive officers.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Timothy J. Barberich .....	60	Executive Chairman
Adrian Adams .....	57	President, Chief Executive Officer
Mark H. N. Corrigan, M.D. ....	50	Executive Vice President, Research and Development
Mark Iwicki .....	41	Executive Vice President, Chief Commercial Officer
Andrew I. Koven .....	50	Executive Vice President, General Counsel and Corporate Secretary
Robert F. Scumaci .....	48	Executive Vice President, Corporate Finance, Administration and Technical Operations
David P. Southwell .....	47	Executive Vice President, Corporate Planning, Development and Licensing and Chief Financial Officer

*Mr. Barberich*, a founder of Sepracor, has served as Chairman of our Board of Directors since 1984. He served as our Chief Executive Officer from 1984 until May 2007. In May 2007, Mr. Barberich became our Executive Chairman. From 1984 until October 1999, Mr. Barberich also served as our President. Mr. Barberich serves as a director of BioSphere Medical, Inc., Gemin X Biotechnologies, Resolviz Pharmaceuticals, Inc., Bionevia Pharmaceuticals, Inc. and Boston Medical Center.

*Mr. Adams* has served as our President and Chief Executive Officer since May 2007. From March 2007 to May 2007, Mr. Adams served as our Chief Operating Officer. From January 2002 until March 2007, Mr. Adams served as the President and Chief Executive Officer of Kos Pharmaceuticals, Inc. and from April 2001 until January 2002 as its President and Chief Operating Officer. Prior to joining Kos Pharmaceuticals, Mr. Adams served as President and Chief Executive Officer of Novartis Pharmaceuticals in Europe. Mr. Adams also served SmithKline Beecham Pharmaceuticals from 1992 to 1999 in various national and international capacities, last serving as President of its Canadian subsidiaries. Mr. Adams has served as a director of Amylin Pharmaceuticals, Inc. since October 2007.

*Dr. Corrigan* has served as our Executive Vice President, Research and Development since April 2003. Prior to joining Sepracor, Dr. Corrigan was Group Vice President of Global Clinical Research and Experimental Medicine at Pharmacia, a pharmaceutical company, from 1998 to 2003. After spending seven years in academic research, Dr. Corrigan joined Upjohn in 1993 and served in several senior management positions in clinical research and development for Upjohn and Pharmacia Upjohn. Dr. Corrigan is board certified in psychiatry and neurology and is a board member of Neuromed Technologies Inc.

*Mr. Iwicki*, has served as our Executive Vice President and Chief Commercial Officer since October 2007. Prior to joining Sepracor, Mr. Iwicki was Vice President, Cardiovascular Business Franchise Head at Novartis from 1998 until October 2007. Prior to his tenure with Novartis, Mr. Iwicki served in sales, marketing and management positions at Merck and Astra Merck Inc. and began his career at Merck & Co. in 1989.

*Mr. Koven* has served as our Executive Vice President, General Counsel and Corporate Secretary since March 2007. Prior to joining Sepracor, Mr. Koven served as Executive Vice President, General Counsel and Corporate Secretary of Kos Pharmaceuticals, Inc. from August 2003 to March 2007. Mr. Koven served as Senior Vice President, General Counsel and Corporate Secretary at Lavipharma Laboratories Inc., from 2000 to August 2003, and he served as Assistant General Counsel of both the Pharmaceutical and Consumer Health divisions of Warner Lambert, and earlier practiced law at Cahill, Gordon and Reindel in New York.

*Mr. Scumaci* has served as our Executive Vice President, Corporate Finance and Administration since February 2001 and as our Treasurer since March 1996. In May 2007, Mr. Scumaci assumed the additional responsibility of leadership of our commercial technical operations. Mr. Scumaci served as our Senior Vice President, Finance and Administration from March 1996 to February 2001 and as our Vice President and Controller from March 1995 until March 1996. From 1987 to 1994, Mr. Scumaci was employed by Ares-Serono Group, a multinational pharmaceutical company, most recently as Vice President, Finance and Administration of North American Operations. Previously, he was associated with Revlon and Coopers & Lybrand in various finance and accounting capacities.

*Mr. Southwell* has served as our Executive Vice President and Chief Financial Officer since October 1995. In May 2007, Mr. Southwell assumed the additional responsibility of leadership of corporate planning, development, and licensing. Mr. Southwell served as our Senior Vice President and Chief Financial Officer from July 1994 to October 1995. From August 1988 until July 1994, Mr. Southwell was employed by Lehman Brothers Inc., a securities firm, in various positions within the investment banking division, most recently in the position of Vice President. Mr. Southwell is Chairman of the Board of BioSphere Medical, serves as a director of PTC Therapeutics, Inc. and is on the MBA Advisory Board of the Tuck School at Dartmouth College.

## PART II

### Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

#### (a) Market for Registrant's Common Equity

Our common stock is traded on the NASDAQ Global Select Market under the symbol SEPR. On February 25, 2008, the closing price of our common stock, as reported on the NASDAQ Global Select Market, was \$22.73 per share. The following table sets forth for the periods indicated the high and low sales prices per share of our common stock as reported by the NASDAQ Global Select Market and, prior to July 1, 2006, the NASDAQ National Market.

	<u>High</u>	<u>Low</u>
<b>2008</b>		
First Quarter (through February 25, 2008) .....	\$30.60	\$22.41
	<u>High</u>	<u>Low</u>
<b>2007</b>		
First Quarter .....	\$62.34	\$46.20
Second Quarter .....	\$56.64	\$40.87
Third Quarter .....	\$42.91	\$25.94
Fourth Quarter .....	\$28.24	\$22.75
	<u>High</u>	<u>Low</u>
<b>2006</b>		
First Quarter .....	\$60.20	\$47.22
Second Quarter .....	\$60.75	\$42.29
Third Quarter .....	\$57.40	\$43.84
Fourth Quarter .....	\$62.88	\$47.74

On February 15, 2008, we had approximately 363 stockholders of record.

#### (b) Dividend Policy

We have never paid cash dividends on our common stock. We currently intend to reinvest our future earnings, if any, for use in the business and do not expect to pay cash dividends.

#### (c) Issuer Purchases of Equity Securities

None.

**Item 6. Selected Financial Data.**

The following selected financial data are derived from our financial statements. The consolidated statement of operations data for the years ended December 31, 2007, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2007 and 2006 have been derived from our audited consolidated financial statements included elsewhere in this annual report on Form 10-K. The consolidated statement of operations data for the years ended December 31, 2006 and 2005 and the consolidated balance sheet data as of December 31, 2006 is derived from the audited restated consolidated financial statements, including the notes thereto, appearing elsewhere in this report. The consolidated statement of operations data for the years ended December 31, 2004 and 2003 and the consolidated balance sheet data as of December 31, 2004 and 2003 have been restated as discussed in footnote (1) of the table below. The unaudited consolidated financial statements, in the opinion of management, include all adjustments necessary for a fair statement of the results for the unaudited periods.

The selected consolidated financial data set forth below should be read in conjunction with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Financial Statements and Supplementary Data” and the related notes included elsewhere in this annual report on Form 10-K. The historical results presented are not necessarily indicative of future results.

See the “Explanatory Note” to this report on Form 10-K and Note U to our consolidated financial statements for more detailed information regarding the restatement of our consolidated financial statements as of December 31, 2006 and 2005 and for each of the fiscal years ended December 31, 2006 and 2005.

**SEPRACOR INC. SELECTED FINANCIAL DATA**

	Year Ended December 31,				
	2007	2006 (as restated)(1)	2005 (as restated)(1)	2004 (as restated)(1)	2003 (as restated)(1)
	(In Thousands, Except Per Share Data)				
STATEMENT OF OPERATIONS					
DATA:					
Revenues:					
Product sales . . . . .	\$1,177,256	\$1,149,374	\$ 749,865	\$ 311,945	\$ 278,854
Royalties . . . . .	47,710	33,759	51,243	52,150	51,487
License fees and other . . . . .	264	—	—	8,946	5,734
Total revenues . . . . .	<u>1,225,230</u>	<u>1,183,133</u>	<u>801,108</u>	<u>373,041</u>	<u>336,075</u>
Costs and expenses:					
Cost of revenue . . . . .	117,155	104,736	67,431	35,427	30,219
Research and development(2) . . . .	263,756	163,488	144,504	159,974	220,224
Selling, general and administrative and patent costs . . . . .	780,865	763,793	626,610	389,417	198,906
Litigation settlement, net . . . . .	34,000	—	—	—	—
Restructuring expense . . . . .	6,921	—	—	—	—
Total costs and expenses . . . . .	<u>1,202,697</u>	<u>1,032,017</u>	<u>838,545</u>	<u>584,818</u>	<u>449,349</u>
Income (loss) from operations . . . . .	22,533	151,116	(37,437)	(211,777)	(113,274)
Other income (expense):					
Interest income . . . . .	46,599	46,589	27,462	8,470	6,179
Interest expense . . . . .	(3,020)	(22,166)	(23,368)	(23,646)	(50,907)
Debt conversion expense(3) . . . . .	—	—	—	(69,768)	—
Gain (loss) on early extinguishment of debt(4) . . . . .	—	—	—	(7,022)	(4,645)
Equity in investee losses(5) . . . . .	(507)	(422)	(665)	(1,485)	(1,921)
Other . . . . .	(1,002)	(300)	(79)	482	157
Gain on sale of affiliate stock(6) . . .	—	—	18,345	—	18,524
Income (loss) before income taxes . .	64,603	174,817	(15,742)	(304,746)	(145,887)
Income taxes . . . . .	6,270	3,656	151	—	—
Net income (loss) . . . . .	<u>\$ 58,333</u>	<u>\$ 171,161</u>	<u>\$ (15,893)</u>	<u>\$ (304,746)</u>	<u>\$ (145,887)</u>
Basic net income (loss) per common share . . . . .					
	\$ 0.55	\$ 1.63	\$ (0.15)	\$ (3.31)	\$ (1.72)
Diluted net income (loss) per common share . . . . .					
	\$ 0.50	\$ 1.48	\$ (0.15)	\$ (3.31)	\$ (1.72)
Shares used in computing basic and diluted net income (loss) per common share:					
Basic . . . . .	106,847	104,943	104,839	92,017	84,639
Diluted . . . . .	116,364	115,508	104,839	92,017	84,639
BALANCE SHEET DATA:					
Cash and short and long-term investments . . . . .					
	\$1,065,619	\$1,166,324	\$ 976,201	\$ 833,912	\$ 840,388
Total assets . . . . .	1,404,726	1,493,793	1,274,497	1,039,118	1,020,225
Long-term debt . . . . .	648,020	721,390	1,161,587	1,161,670	1,040,789
Stockholders' equity (deficit) . . . . .	\$ 176,413	\$ 40,184	\$ (204,072)	\$ (349,878)	\$ (630,138)

- (1) See Note U, "Restatement of Financial Statements Based on Review of Government Pricing," in the Notes to Consolidated Financial Statements.

The following table sets forth the impact of the product revenues reduction on our historical financial statements disclosed in the Sepracor Inc. Selected Financial Data table, set forth above, for the fiscal years ended December 31, 2006, 2005, and 2004 and 2003.

	Year Ended December 31,			
	2006	2005	2004	2003
	(In Thousands, Except Per Share Data)			
Consolidated Statement of Operations changes:				
Product sales				
As previously reported	\$1,162,775	\$769,685	\$ 319,781	\$ 286,819
As restated	\$1,149,374	\$749,865	\$ 311,945	\$ 278,854
Income (loss) from operations				
As previously reported	\$ 164,517	\$ (17,617)	\$ (203,941)	\$ (105,309)
As restated	\$ 151,116	\$ (37,437)	\$ (211,777)	\$ (113,274)
Income (loss) before income taxes				
As previously reported	\$ 188,218	\$ 4,078	\$ (296,910)	\$ (137,922)
As restated	\$ 174,817	\$ (15,742)	\$ (304,746)	\$ (145,887)
Net income (loss)				
As previously reported	\$ 184,562	\$ 3,927	\$ (296,910)	\$ (137,922)
As restated	\$ 171,161	\$ (15,893)	\$ (304,746)	\$ (145,887)
Basic net income (loss) per common share				
As previously reported	\$ 1.76	\$ 0.04	\$ (3.23)	\$ (1.63)
As restated	\$ 1.63	\$ (0.15)	\$ (3.31)	\$ (1.72)
Diluted net income (loss) per common share				
As previously reported	\$ 1.60	\$ 0.03	\$ (3.23)	\$ (1.63)
As restated	\$ 1.48	\$ (0.15)	\$ (3.31)	\$ (1.72)

We recorded a prior period adjustment to increase accumulated deficit as of the end of the year ended December 31, 2002 by \$3.0 million for the cumulative effect of the error.

- (2) Research and development costs for 2007 include the \$75.0 million upfront payment to Bial.
- (3) Represents inducement costs associated with our conversion of \$177.2 million of our 0% Series A notes due 2008 and \$352.0 million of our 0% Series B notes due 2010 in 2004.
- (4) Represents a loss on our redemption in 2004 of the then remaining outstanding \$430.0 million principal amount of our 5.75% convertible subordinated notes due 2006, a loss on our redemption in 2003 of the remaining \$111.9 million principal amount of our 7% convertible subordinated debentures due 2005 and a gain from our repurchase in 2002 of approximately \$131.1 million of our 7% convertible subordinated debentures in privately negotiated transactions.
- (5) Represents our portion of BioSphere Medical, Inc. losses.
- (6) Represents a gain on the sale of approximately 688,000 and 1.2 million shares of Vicuron Pharmaceuticals Inc. common stock in 2005 and 2003, respectively.

## Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

### Restatement of Prior Period Financial Information

In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. As a follow up to this

disclosure to CMS, our management, with the oversight of our Audit Committee, is reviewing our government pricing activities affected by the material weakness in our internal controls related to these potential errors. We restated our financial statements for the years ended December 31, 2006 and 2005 and the unaudited quarterly information in Note T in our consolidated financial statements for the fiscal quarters ended March 31, June 30 and September 30, 2007 and 2006 to reduce the amount of product revenue earned during such periods. The amounts by which we have reduced revenues for contingent rebates were based on management's best estimates and assumptions made prior to any concurrence by CMS. These amounts may change as a result of future communications with CMS, and we cannot be certain that we have not overestimated the amount of additional rebates we may be required to pay, that the amount of any additional rebate payments or other payments we may owe will not exceed our current estimates, or that we will not be subject to fines, penalties or interest.

The discussion and analysis set forth in this Item 7 has been amended to reflect the restatement as described in the prior paragraph, in the Explanatory Note at the beginning of this Annual Report on Form 10-K and in Note U to our consolidated financial statements. The aggregate amount by which we have reduced revenue in prior periods is approximately \$60.2 million. The amount by which we have reduced revenues for the first three quarters of 2007, combined, and the fiscal years ended December 31, 2006 and 2005 is approximately \$8.2 million, \$13.4 million and \$19.8 million, respectively. For this reason, the discussion and data set forth in this section may not be comparable to discussions and data in our previously filed reports.

### **Executive Overview**

We are a research-based pharmaceutical company focused on discovering, developing and commercializing differentiated products that address large and growing markets and unmet medical needs and are prescribed principally by primary care physicians and certain specialists.

Our currently marketed products are:

- XOPENEX® (levalbuterol HCl) Inhalation Solution, a short-acting bronchodilator, for the treatment or prevention of bronchospasm in patients six years of age and older with reversible obstructive airway disease;
- XOPENEX HFA® (levalbuterol tartrate) Inhalation Aerosol, a hydrofluoroalkane, or HFA, metered-dose inhaler, or MDI, for the treatment or prevention of bronchospasm in adults, adolescents and children four years of age and older with reversible obstructive airway disease;
- BROVANA® (arformoterol tartrate) Inhalation Solution, a long-acting, twice-daily (morning and evening), maintenance treatment of bronchoconstriction in patients with COPD, including chronic bronchitis and emphysema; and
- LUNESTA® (eszopiclone) for the treatment of insomnia in adults.

We market these products in the United States to primary care physicians, allergists, pulmonologists, pediatricians, hospitals, psychiatrists and sleep specialists, as appropriate, primarily through our sales organization comprised of approximately 1,600 sales professionals. In addition, we recently obtained from Nycomed the exclusive U.S. distribution rights to two products that have been approved by the FDA, OMNARIS AQ nasal spray and ALVESCO HFA Inhalation Aerosol, which we expect to launch commercially during 2008.

Factors that will be critical for us in achieving near-term success include our ability to:

- increase our LUNESTA revenues, despite increasing competition;
- grow XOPENEX Inhalation Solution revenues outside of the Medicare market by maintaining targeted sales and marketing efforts aimed at the retail and hospital market segments. Revenues

from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of restrictions on the Medicare Part B reimbursement amount for XOPENEX Inhalation Solution;

- continue to increase our XOPENEX HFA revenues;
- successfully market and sell BROVANA, particularly in the home health care market segment, which could be adversely affected by potential restrictions on Medicare Part B reimbursement or changes in the Medicare Part B reimbursement amount for BROVANA;
- manage expenses effectively to help preserve profitability and positive cash flow from operations; and
- maintain patent protection for our products, particularly for XOPENEX Inhalation Solution for which four ANDAs have been submitted to the FDA.

We believe that success in each of these areas should allow us to continue to be profitable in the near term and provide us the ability to repay our outstanding convertible debt of \$720.8 million. If not converted, repurchased at the noteholders' or our option, or otherwise refinanced earlier, the principal amount of this debt becomes due as follows:

<u>Principal Amount of Convertible Debt</u>	<u>Maturity Date</u>
\$72,800,000 .....	2008
\$148,020,000 .....	2010
\$500,000,000 .....	2024(1)

- (1) This note may be converted into cash at the option of the noteholders at certain specified time periods, the first of which is in October 2009.

Our long-term success depends in part on our ability to successfully develop or acquire and commercialize new product candidates.

Our material sources of revenue in 2007 were product revenues from LUNESTA, XOPENEX Inhalation Solution and XOPENEX HFA and to a lesser extent, revenues from BROVANA and royalty revenues received from sales of ALLEGRA, CLARINEX and XYZAL/XUSAL. We expect that sales of LUNESTA and XOPENEX Inhalation Solution will represent the majority of our total revenues in 2008. We do not have long-term sales contracts with our customers and we rely on purchase orders for sales of our products. Reductions, delays or cancellations of orders for LUNESTA, XOPENEX Inhalation Solution or XOPENEX HFA could adversely affect our operating results. If sales of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA do not meet our expectations, we may not have sufficient revenue to achieve our business plan and our business will not be successful.

In 2008, we expect to be profitable for the year on an operating and net income basis. We expect sales and marketing expenses to increase as compared to 2007 as we incur increasing sales and marketing costs related to the anticipated product commercialization of OMNARIS AQ and ALVESCO HFA, including the anticipated increase in sales force capacity in order to accommodate the launch of these two products, as well as continued revenue growth in our currently marketed products. We expect to continue to invest in marketing programs related to LUNESTA, BROVANA and XOPENEX and incur significant costs related to expected OMNARIS AQ and ALVESCO HFA commercial introductions. We expect research and development expenses to increase as compared to 2007 as we continue to invest in research and development activities relating to studies for LUNESTA, XOPENEX HFA, and BROVANA, and for continued development of our earlier stage drug candidates, as well as increased drug discovery efforts and development activities for the ciclesonide pipeline. As part of our business strategy, in 2008, and in the future, we expect to consider and, as



appropriate, consummate acquisitions of other technologies, product candidates, approved products, and/or businesses. We can provide no assurance that we will be successful in achieving any such acquisitions.

**Significant 2008 and 2007 Developments** In early 2008 and 2007, our key developments included the following:

#### **Corporate Development & Licensing**

- In January 2008, we entered into an agreement with Nycomed for the exclusive U.S. distribution, development and commercialization in the United States, its territories and possessions of Nycomed's compound ciclesonide, and products incorporating such compound, including ALVESCO HFA Inhalation Aerosol metered-dose inhaler, for use in the treatment of asthma, and OMNARIS AQ nasal spray for use in the treatment of allergic rhinitis. Under the agreement, we paid Nycomed an upfront payment of \$150.0 million in February 2008 and may be required to make subsequent payments of up to \$280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. Nycomed will also receive compensation for supplying finished product pursuant to the agreement, including a supply price for the products, which will be based on Nycomed's manufacturing costs plus a percentage of such costs, and quarterly royalty payments based on our net sales of the products.
- In December 2007, we entered into a license agreement with Bial for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound, BIA 2-093, which we now refer to as SEP-0002093. Pursuant to the agreement, we paid Bial an upfront payment of \$75.0 million and are required to make subsequent payments upon accomplishment of various development and regulatory milestones, which could include up to an additional \$100.0 million if all milestones are met. Bial will also receive compensation for providing finished product pursuant to a supply agreement that is expected to be entered into by the parties, which will be calculated as a percentage of the average net selling price for finished tablets, and milestone payments upon FDA approval of additional indications, if any.
- In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product, which we market as LUNESTA in the United States, for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territory primarily as LUNIVIA brand eszopiclone for the treatment of insomnia. Under this agreement, we received an initial payment of \$20 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us \$155 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties that escalate upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement that is expected to be entered into by the parties.
- In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product, which we market as LUNESTA in the United States. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an initial milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

## **Directors & Officers**

- In December 2007, we announced that Timothy J. Barberich will retire as an executive of our company prior to May 13, 2008 and plans to serve as our advisor through December 2009. Mr. Barberich also intends to continue to serve as Chairman of our Board of Directors, contingent on his election as a director at the 2008 annual meeting of our shareholders.
- In November 2007, Lisa Ricciardi was elected as a new member of our Board of Directors.
- In October 2007, Mark Iwicki was elected to the newly-created position of Executive Vice President, Chief Commercial Officer.
- In May 2007, Adrian Adams was elected to the role of President and Chief Executive Officer. Mr. Adams previously served as our President and Chief Operating Officer and assumed the Chief Executive Officer role from Mr. Barberich.
- In March 2007, W. James O'Shea resigned as our President and Chief Operating Officer and was elected Vice Chairman. Mr. O'Shea ceased acting in this capacity on August 31, 2007. In addition, effective March 1, 2007, our board elected Adrian Adams to the positions of President and Chief Operating Officer and Andrew I. Koven to the positions of Executive Vice President, General Counsel and Corporate Secretary. The board, upon the recommendation of the nominating and corporate governance committee, also elected Mr. Adams to the Board of Directors, as a Class II director. Douglas E. Reedich, our former Senior Vice President, Legal Affairs, was employed by us through December 31, 2007 in order to ensure an orderly transition in the handling of our legal matters.

## **Litigation and Investigations**

- In November 2007, the SEC notified us that the investigation concerning our historical stock option granting practices had been completed and that no enforcement action was being recommended.
- In October 2007, we reached a settlement with the parties to both the state and Federal derivative actions brought against us (as a nominal defendant) and certain of our current and former officers and directors related to certain stock option grants and alleged violations of Federal securities laws, that provided for the dismissal of both actions. The settlement resolved all claims and included no finding of wrongdoing on the part of any of the defendants and no cash payment other than attorneys' fees. As part of the settlement, we have adopted, and are in the process of completing the implementation of, stock option grant and other procedures that reflect developing best practices. The settlement became final and effective in January 2008 upon final approval by the state court and entry of dismissal with prejudice by the Federal court.
- In October 2007, we reached a final settlement agreement with Tharos Laboratories, Inc., or Tharos, with respect to the litigation brought against us by Tharos alleging trademark infringement, dilution, unfair competition, false advertising and false designation of origin arising out of our use of our silk luna moth design in connection with LUNESTA. As a result of this settlement agreement, the case has been dismissed.
- In June 2007, we filed in the United States District Court for the District of Massachusetts, or the Court, a Stipulation of Settlement regarding two securities class action lawsuits, or class actions, pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. The class actions, which were filed on behalf of certain purchasers of our equity and debt securities, or the plaintiffs, allege that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. The Stipulation of Settlement

contains no admission of wrongdoing. Sepracor and the other defendants have always maintained and continue to believe that we did not engage in any wrongdoing or otherwise commit any violation of Federal or state securities laws or other laws. However, given the potential cost and burden of continued litigation, we believe the settlement was in our best interests and the best interests of our stockholders. Under the terms of the Stipulation of Settlement, in June 2007 we paid into escrow \$52.5 million in settlement of the class actions and, in July 2007, received an \$18.5 million reimbursement from our insurance carriers. We recorded the litigation settlement expense of \$34.0 million, relating to this matter, during the quarter ended March 31, 2007. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow. Pursuant to the final judgment entered by the Court, the Court dismissed the class actions with prejudice, and the plaintiffs are deemed to have released all claims against us.

- In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey, L.P. and Dey, Inc., referred to collectively as Dey, alleging that the manufacture and sale of BROVANA infringes or will induce infringement of a single U.S. patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaim to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. Under the current scheduling order, trial will begin no earlier than January 12, 2009.

#### **Regulatory**

- In November 2007, we announced that CMS established a product-specific billing code, or J Code, for BROVANA under the Medicare Part B benefit, which became effective on January 1, 2008. In April 2007, we announced the commercial availability of BROVANA for the treatment of COPD.
- In July 2007, we submitted a Marketing Authorization Application, or MAA, to the European regulatory authorities for LUNIVIA for the treatment of insomnia. Approval of the MAA, which is the European Union equivalent of a New Drug Application, or NDA, in the United States, would allow authorization to market LUNIVIA in the European Union. Pursuant to our agreement with GSK, we are responsible for supporting the MAA until final approval, or such earlier date mutually agreed upon by the parties, and GSK is responsible for supporting the MAA thereafter. We received a consolidated report from the reviewing MAA rapporteurs in December 2007 and responded to them in early 2008. Approval of the MAA is targeted for the fourth quarter of 2008.
- In June 2007, we announced that CMS determined that, based on its interpretation of the statutory language of the Medicare Prescription Drug Improvement and Modernization Act of 2003, or MMA, it was required to discontinue the stand-alone reimbursement for XOPENEX Inhalation Solution and generic albuterol, which had been in place since January 2005, and instead calculate the reimbursement for XOPENEX Inhalation Solution and generic albuterol based on the blended weighted average selling price, or ASP, for the two products. This new reimbursement became effective on July 1, 2007. Using a blended weighted ASP for XOPENEX Inhalation Solution results in reimbursement for the product that is considerably lower than the published selling price for the product in the wholesaler distribution channel. The new reimbursement rate is subject to change quarterly based upon the respective contribution of commercial sales of XOPENEX Inhalation Solution and generic albuterol to the quarterly blended weighted ASP calculation. This quarterly ASP calculation is mandated by the MMA.

Revenues from the sale of XOPENEX Inhalation Solution have been, and we expect will continue to be, adversely affected on a comparable basis as a result of this change.

In addition, on December 29, 2007, President Bush signed into law legislation mandating that XOPENEX Inhalation Solution and generic albuterol be reimbursed at the lower of their stand-alone weighted ASP and the blended weighted ASP for XOPENEX Inhalation Solution and generic albuterol. The effect of this legislation is that XOPENEX Inhalation Solution will continue to be reimbursed at the blended rate and generic albuterol will be reimbursed at its stand-alone weighted ASP. The legislation goes into effect on April 1, 2008.

#### **Other Key Developments**

- In February 2008, intend to increase our sales force capacity by at least 200 sales professionals in order to accommodate the commercialization of OMNARIS AQ and ALVESCO HFA.
- In January 2008, we notified CMS that we had identified potential errors in our determination of the best price used to calculate Medicaid rebate amounts in prior periods. As a follow up to this disclosure to CMS, our management, with the oversight of our Audit Committee, is reviewing our government pricing activities affected by the material weakness in our internal controls related to these potential errors.
- In October 2007, we announced that we had decided to reduce our sales force by approximately 300 positions. The decision was based on our evaluation of the structure, size and allocation of our direct sales force at that time and was intended to result in cost savings in fiscal year 2008. As of December 31, 2007, this sales force reduction was completed.
- In February 2007, we paid in full \$440.0 million in aggregate principal amount of outstanding 5% convertible subordinated debentures, which matured on February 15, 2007, plus approximately \$11.0 million in accrued interest.

#### **Revenue-Related Agreements**

*Fexofenadine HCl.* In July 1993, we licensed to Hoechst Marion Roussel, Inc., now sanofi-aventis (formerly Aventis), our U.S. patent rights covering fexofenadine HCl. In October 1996, Aventis commercially introduced ALLEGRA, which is fexofenadine HCl. Since March 1, 1999, we have been entitled to receive royalties on fexofenadine product sales in countries where we have patents related to fexofenadine. In February 2001, we began earning royalties on fexofenadine sales in the U.S. However, since the introduction of a generic version of ALLEGRA in the United States during the third quarter of 2005, we have ceased to earn royalties on sales of ALLEGRA in the United States. We are currently receiving royalties from sanofi-aventis for sales of ALLEGRA in Japan, Canada and Australia and in certain E.U. member states. We recorded approximately \$25.2 million, \$16.6 million and \$36.9 million of royalty revenues under these agreements in 2007, 2006 and 2005, respectively.

*Desloratadine.* In December 1997, we licensed to Schering-Plough Corporation exclusive worldwide rights to our patents and patent applications relating to desloratadine, an active-metabolite of loratadine, which is marketed by Schering-Plough as CLARITIN. In January 2002, Schering-Plough commercially introduced CLARINEX brand desloratadine 5 mg tablets for the treatment of seasonal allergic rhinitis, or SAR, in adults and children twelve years of age and older. In February 2002, Schering-Plough received FDA approval to market CLARINEX tablets for the treatment of chronic idiopathic urticaria, or CIU, in adults and children twelve years of age and older. Under the terms of our license agreement with Schering-Plough, we are currently receiving royalties on sales of CLARINEX in countries in which we hold patents. We recorded approximately \$16.5 million, \$12.2 million and \$9.4 million of royalty revenue under this agreement in 2007, 2006 and 2005,

respectively. Beginning in October 2007, the contractual royalty rate increased with respect to sales in the United States.

*Levocetirizine.* In February 2006, we entered into a license agreement with UCB S.A. relating to levocetirizine. Under this agreement, we have exclusively licensed to UCB S.A. all of our patents and patent applications in the United States regarding levocetirizine and royalties are payable to us on sales of levocetirizine products in the United States. In September 2006, UCB and sanofi-aventis announced they entered into an agreement to co-promote XYZAL in the United States. In February 2008, UCB announced that the FDA approved its NDA for XYZAL 0.5 mg/ml solution. XYZAL tablets received FDA approval in May 2007. Pursuant to our agreement with UCB Farchim S.A., we also earn royalties on sales of levocetirizine outside of the United States. Levocetirizine is currently marketed by UCB under the brand names XYZAL and XUSAL in the E.U. for treatment of symptoms of seasonal and perennial allergic rhinitis, persistent allergic rhinitis and CIU in adults and children six years of age and older. We recorded approximately \$6.0 million, \$5.0 million and \$4.9 million of royalty revenue under the agreement with UCB in 2007, 2006 and 2005, respectively.

*Eszopiclone.* In September 2007, we entered into an agreement with GSK for the development and commercialization of our eszopiclone product, which we market as LUNESTA in the United States, for all markets worldwide excluding the United States, Canada, Mexico and Japan. Our eszopiclone product will be marketed by GSK in its territory primarily as LUNIVIA brand eszopiclone for the treatment of insomnia. Under this agreement, we received an initial payment of \$20.0 million and are entitled to receive additional payments upon accomplishment of various milestones. If all milestones are met, GSK will be obligated to pay us \$155.0 million in aggregate license and milestone payments. We are also entitled to receive double-digit royalties that escalate upon increased product sales, and compensation for supplying the product to GSK pursuant to a supply agreement that is expected to be entered into by the parties.

In July 2007, we entered into an agreement with Eisai for the development and commercialization of our eszopiclone product. Under this agreement, Eisai will be responsible for completing remaining clinical trials necessary for attaining marketing approval from the Japanese regulatory authorities and, contingent on obtaining regulatory approval, commercialization of the product in Japan. We received an initial milestone payment and will be entitled to receive subsequent payments upon accomplishment of various development, regulatory and pricing milestones, as well as royalties on product sales. We will also be responsible for, and will receive compensation in connection with, the manufacture and supply of bulk tablets and/or active ingredient.

In September 1999, we entered into an agreement with sanofi-aventis' predecessor, Rhone-Poulenc Rorer SA, under which we exclusively licensed preclinical, clinical and post-marketing surveillance data package relating to zopiclone, its isomers and metabolites, to develop, make, use and sell eszopiclone in the United States. Zopiclone is marketed by sanofi-aventis in approximately 80 countries worldwide under the brand names of IMOVANE® and AMOBAN®. Under this agreement, Rhone-Poulenc Rorer assigned all U.S. patent applications relating to (S)-zopiclone to us. Under an amended agreement, we have the right to read and reference sanofi-aventis' regulatory filings related to zopiclone outside of the United States for the purpose of development and regulatory registration of eszopiclone outside of the United States, and sanofi-aventis has assigned to us the foreign counterparts to the U.S. patent covering eszopiclone and its therapeutic use. Also as part of the amendment, we permitted sanofi-aventis to assign our obligation to pay a royalty on sales of LUNESTA in the United States to a third party.

## Results of Operations

### Year Ended December 31, 2007 Compared to 2006 (Restated)

#### Revenues

Product sales were \$1,177.3 million in 2007 as compared with \$1,149.4 million in 2006, an increase of approximately 2%.

Sales of LUNESTA were \$600.9 million in 2007, as compared to \$565.4 million in 2006, an increase of approximately 6%. The increase is primarily due to a 7% increase in net selling price, which resulted from a gross price increase of approximately 13%, offset by an increase in sales discounts and allowance of approximately 5%. Units sold decreased by just under 1%. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales."

Sales of XOPENEX Inhalation Solution were \$487.2 million in 2007 as compared with \$543.0 million in 2006, a decrease of approximately 10%. The decrease was primarily due to units sold decreasing by approximately 4% and a decrease in net selling price of 6%. The net selling price decrease resulted from a realized gross price increase of approximately 7%, offset by an increase in sales discounts and allowances of approximately 10%. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales."

Sales of XOPENEX HFA were \$74.9 million in 2007, as compared to \$41.0 million in 2006, an increase of approximately 83%. The increase is primarily due to a 30% increase in net selling price, which resulted from a decrease in sales discounts and allowances and a 40% increase in units sold. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales."

Sales of BROVANA were \$14.3 million in 2007, as compared to \$0 in 2006. We introduced BROVANA commercially in April 2007. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales."

*Analysis of gross sales to net sales*—The following table presents the adjustments deducted from total gross sales to arrive at total net sales:

	For the Years Ended December 31,					
	2007	% of Sales	2006 (as restated)(1)	% of Sales	Change	% Change
			(Dollars in Thousands)			
Gross sales . . . . .	\$1,594,467	100.0%	\$1,435,363	100.0%	\$159,104	11%
Adjustments to gross sales:						
Payment term discounts . . . . .	31,939	2.0%	29,264	2.0%	2,675	9%
Wholesaler fee-for-service . . . . .	28,629	1.8%	42,048	2.9%	(13,419)	(32)%
Government rebates and contractual discounts . . . . .	312,686	19.6%	190,206	13.3%	122,480	64%
Returns . . . . .	29,606	1.9%	20,255	1.4%	9,351	46%
Other (includes product introduction discounts) . . . . .	14,351	0.9%	4,216	0.3%	10,135	240%
Sub-total adjustments . . . . .	417,211	26.2%	285,989	19.9%	131,222	46%
Net sales . . . . .	<u>\$1,177,256</u>	<u>73.8%</u>	<u>\$1,149,374</u>	<u>80.1%</u>	<u>\$ 27,882</u>	<u>2%</u>

- (1) As a result of the restatement, the 2006 dollar value of government rebates and contractual discounts increased by \$13.4 million and, as a percentage of net sales, increased from 12.3% to 13.3%.

The increase in adjustments to gross sales as a percentage of gross sales in 2007 as compared to 2006 primarily reflects an overall increase in government and commercial rebates and discounts as a result of (i) an increase in Medicaid discounts that we offered on the sales of XOPENEX Inhalation Solution, LUNESTA, and XOPENEX HFA, (ii) an increase in discounts given through Medicare Part B program that we offered on the sales of XOPENEX Inhalation Solution as a result of the CMS bundling decision, which created a new reimbursement code for XOPENEX Inhalation Solution, (iii) an increase in managed care commercial discounts we offered on the sales of LUNESTA and XOPENEX HFA, (iv) an increase in discounts given through Medicare Part D program that we offered on the sales of LUNESTA, and (v) a decrease in XOPENEX HFA units sold under a government contract with the Veterans Administration in 2007 as compared to 2006. Returns also increased in 2007 as compared to 2006, which is primarily due to a higher rate of return of XOPENEX Inhalation Solution as a result CMS' decision to discontinue the stand-alone reimbursement for the product and also higher returns of LUNESTA, primarily in the 1mg tablets and all hospital units doses. In addition, other discounts increased as we increased the utilization of coupon programs, primarily related to XOPENEX HFA. Partially offsetting these increases in adjustments to gross sales as a percentage of gross sales was a decrease in wholesaler fee-for-service charges primarily related to credits earned due to LUNESTA and XOPENEX Inhalation Solution gross price increases during 2007.

Royalties and license fees were \$48.0 million in 2007 as compared with \$33.8 million in 2006, respectively, an increase of approximately 42%.

Royalties earned on the sales of ALLEGRA under our agreement with sanofi-aventis increased to \$25.2 million in 2007 as compared to \$16.6 million in 2006, an increase of approximately 52%. The increase is primarily the result of increased sales in Japan and sanofi-aventis' product commercialization of a 180 mg dosage strength of ALLEGRA.

Royalties earned on sales of CLARINEX under our agreement with Schering-Plough increased to \$16.5 million in 2007 from \$12.2 million in 2006, an increase of approximately 35%. The increase is primarily the result of a contractual royalty rate increase that took effect in October 2007.

Royalties earned on sales of XYZAL/XUSAL under our agreement with UCB increased to \$6.0 million in 2007 as compared to \$5.0 million in 2006, an increase of approximately 21%.

License fees recognized on our GSK and Eisai agreements for the development and commercialization of our eszopiclone product, which we entered into in the second half 2007, were \$264,000 in 2007 as compared to \$0 in 2006.

A number of our foreign patents that we have out-licensed to Schering-Plough, sanofi-aventis and UCB in connection with the sale of CLARINEX, ALLEGRA and XYZAL/XUSAL, respectively, are subject to patent invalidity claims. If patent-based exclusivity is lost for one or more of these products in any foreign jurisdiction, our rights to receive royalty revenue with respect to such product in the relevant jurisdiction will terminate, which may have a material adverse effect on our business, financial condition and results of operations.

#### *Costs of Revenues*

Cost of products sold was \$115.8 million in 2007 as compared with \$103.8 million in 2006, an increase of approximately 12%.

Cost of LUNESTA sold as a percentage of LUNESTA gross sales was approximately 6% in 2007 and 2006, principally due to royalties we pay to a third party on net sales of LUNESTA.

Cost of XOPENEX Inhalation Solution sold as a percentage of XOPENEX Inhalation Solution gross sales was approximately 7% in 2007 and 2006.

Cost of XOPENEX HFA sold as a percentage of XOPENEX HFA gross sales was approximately 15% in 2007 and 2006. Included in the costs of XOPENEX HFA sold is a royalty paid on net sales of XOPENEX HFA to 3M, our third-party finished goods manufacturer of the product.

Cost of BROVANA sold as a percentage of BROVANA gross sales was approximately 15% in 2007. We introduced BROVANA commercially in April 2007.

Cost of royalties earned was \$1.3 million for 2007, compared with \$1.0 million for 2006. The cost of royalties in both periods relates to an obligation to a third party as a result of royalties we earn from Schering-Plough based on its sales of CLARINEX. This increase in obligations to the third party is due to the increase in royalties earned in 2007 as compared to 2006.

#### *Research and Development*

Research and development expenses were \$263.8 million in 2007 as compared to \$163.5 million in 2006, an increase of approximately 61%. The increase is primarily due to the \$75.0 million fee we paid to Bial pursuant to the license agreement for BIA 2-093, which we now refer to as SEP 0002093, increased spending on two of our early stage programs, SEP-227162 and SEP-225441, the LUNESTA Phase IIIb/IV and pediatric programs and increased drug discovery efforts.

In 2008, we intend to significantly increase research and development expenditures over 2007. We expect our principal research and development activities will relate to the following programs; (1) drug discovery; (2) LUNESTA; (3) SEP-225441; (4) ciclesonide pipeline; (5) SEP-225289; and (6) SEP-0002093.

Drug development and approval in the United States is a multi-step process regulated by the FDA. The process begins with the filing of an IND which, if successful, allows the opportunity for study in humans, or clinical study, of the potential new drug. Clinical development typically involves three phases of study: Phase I, II and III. The most significant costs in clinical development are in Phase III clinical trials, as they tend to be the longest and largest studies in the drug development process. Following successful completion of Phase III clinical trials, an NDA must be submitted to, and accepted by, the FDA, and the FDA must approve the NDA prior to commercialization of the drug. We may elect either on our own, or at the request of the FDA, to conduct further studies that are referred to as Phase IIIB and IV studies. Phase IIIB studies are initiated and either completed or substantially completed while the NDA is under FDA review. These studies are conducted under an IND. Phase IV studies, also referred to as post-marketing studies, are studies that are initiated and conducted after the FDA has approved a product for marketing. Phase IV studies may be requested by the FDA either before or after the FDA has approved an NDA. These studies may also be independently initiated by the company whose NDA has been approved. The FDA uses post-marketing studies to gather additional information about a product's safety, efficacy or optimal use. Successful development of our product candidates is highly uncertain. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. The lengthy process of seeking FDA approvals, and subsequent compliance with applicable statutes and regulations, require the expenditure of substantial resources. Any failure by us to obtain, or delay in obtaining, regulatory approvals could materially adversely affect our business. We cannot assure you that we will obtain any approval required by the FDA on a timely basis, if at all.

For additional discussion of the risks and uncertainties associated with completing development of potential product candidates, see "Risk Factors".

Below is a summary of development of our products and product candidates that represent 10% or more of our direct project research and development spending for the year ended December 31, 2007. The "Estimate of Completion of Phase" column contains forward-looking statements regarding expected timing of completion of product development phases. Completion of product development, if successful, culminates in the submission of an NDA to the FDA; however, there can be no assurance that the FDA will accept for filing, or approve, any NDA. The actual timing of completion of phases could differ materially from the estimates provided in the table. In the table below, the three FDA-approved products and two product candidates listed accounted for approximately 81% of our



direct project research and development spending in 2007. No other product candidate accounted for more than 9% of our direct research and development spending in 2007.

Product or Product Candidate	Indication	Phase of Development	Estimate of Completion of Phase
LUNESTA (eszopiclone) . . . . .	Insomnia	*	*
XOPENEX HFA (levalbuterol tartrate) . . . . .	Respiratory—Asthma	**	**
BROVANA (arformoterol tartrate) . . . . .	Respiratory—COPD	***	***
SEP-225289 . . . . .	Depression	Phase II	2008
SEP-227162 . . . . .	Depression	Phase I	2008

\* We commercially introduced LUNESTA in April 2005.

\*\* We commercially introduced XOPENEX HFA in December 2005.

\*\*\* We commercially introduced BROVANA in April 2007.

Below is a summary of expenditure information related to our products and product candidates representing 10% or more of our direct project research and development spending during the year ended December 31, 2007 and 2006, as well as the costs incurred to date on these projects. The costs in this analysis include only direct costs and do not include certain indirect labor, overhead, share-based compensation, up-front license fees, milestone payments, or other costs that benefit multiple projects. As a result, fully-loaded research and development cost summaries by project are not presented.

	Project costs for the year ended December 31, 2007	Project costs through December 31, 2007	Project costs for the year ended December 31, 2006	Project costs through December 31, 2006
	(In Thousands)			
LUNESTA (eszopiclone) . . . . .	\$25,074	\$245,097	\$20,301	\$220,023
XOPENEX HFA (levalbuterol tartrate) . . . . .	6,209	175,507	12,507	169,298
BROVANA (arformoterol tartrate) . . . . .	14,837	188,768	12,353	173,931
SEP-225289 . . . . .	11,083	24,193	9,041	13,110
SEP-227162 . . . . .	12,844	20,984	6,394	8,140

Due to the length of time necessary to develop a product, uncertainties related to the ability to obtain governmental approval for commercialization, and difficulty in estimating costs of projects, we do not believe it is possible to make accurate and meaningful estimates, with any degree of accuracy, of the ultimate cost to bring our product candidates to FDA approved status.

#### *Selling, Marketing and Distribution*

Selling, marketing and distribution expenses were \$699.3 million in 2007 as compared with \$691.7 million in 2006, an increase of approximately 1%. The increase is primarily attributable to an increase in salary and other compensation related expense as a result of hiring additional sales representatives and management in the second quarter of 2006 to support our marketed products, in addition to increased costs associated with our April 2007 commercialization of BROVANA. These increases were offset by a decrease in marketing, advertising and promotional expenses primarily related to costs to support LUNESTA.

In 2008, we expect sales and marketing expenses to increase over 2007 as a result of the expected commercial introduction of OMNARIS AQ in the first half of 2008 and the expected commercial introduction of ALVESCO HFA in the second half of 2008, offsetting any anticipated 2008 savings from the restructuring of the sales force in the fourth quarter of 2007.

### *General and Administrative*

General and administrative costs were \$81.5 million in 2007 as compared with \$72.1 million in 2006, an increase of approximately 13%. The increase is largely due to an increase in legal fees of approximately \$8.7 million related to patent support and litigation costs.

### *Litigation Settlement*

Litigation settlement expense was \$34.0 million in 2007 compared with \$0 in 2006. In June 2007, we filed in the Court a Stipulation of Settlement regarding two class actions pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. As previously disclosed, the class actions alleged that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of tecastemizole by the FDA. Under the terms of the Stipulation of Settlement, in June 2007, we paid into escrow \$52.5 million in settlement of the class actions and, in July 2007, received an \$18.5 million reimbursement from our insurance carriers. The settlement is now final and the total settlement amount has been released from escrow. We recorded the litigation settlement expense of \$34.0 million relating to this matter during the quarter ended March 31, 2007.

### *Restructuring Expense*

Restructuring expense was \$6.9 million in 2007 compared to \$0 in 2006. During the quarter ended December 31, 2007, we completed an evaluation of our sales force structure, size and allocation in an attempt to maximize efficiency of our sales force. This evaluation resulted in a decision to restructure and re-align our sales force. The costs associated with the restructuring were employee related items primarily relating to severance costs for \$6.5 million and contract terminations on excess leased computer equipment and company cars for \$428,000. All associated costs are expected to be paid by the end of the second quarter of 2008.

### *Other Income (Expense)*

Interest income was \$46.6 million in both 2007 and 2006. Our monthly average cash and investment balance was approximately \$918.0 million and \$990.2 million for the years ended December 31, 2007 and 2006, respectively. For 2007 and 2006, the average annualized interest rate that we earned on our investments was 5.1% and 4.7%, respectively.

Interest expense was \$3.0 million in 2007 as compared with \$22.2 million in 2006. The expense in both periods is primarily related to the interest we paid on our 5% convertible subordinated debentures due 2007, which were paid in full in February 2007.

Equity in investee losses were \$507,000 in 2007 as compared with \$422,000 in 2006. The equity in investee loss in 2007 and 2006 represents our portion of the losses of BioSphere Medical, Inc.

### *Income Taxes*

Income tax expense was \$6.3 million in 2007 as compared to \$3.7 million in 2006. Income tax expense in 2007 and 2006 includes Federal and state alternative minimum tax, or AMT, state income taxes and foreign income tax in 2007. Although we had Federal and state tax net operating loss carryforwards as of December 31, 2007 and 2006, the utilization of these loss carryforwards is limited in the calculation of AMT. The possible adverse impact to our XOPENEX Inhalation Solution sales if an "at risk" generic launch were to occur or we are unable to successfully defend our patents rights and increased sales and marketing expenses as a result of the expected commercial introduction of OMNARIS AQ in the first half of 2008 and the expected commercial introduction of ALVESCO HFA in the second half of 2008, management continues to conclude a valuation allowance is required for the full amount of our deferred tax asset. If in the future, we determine based on our future profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the

related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods. Such release of the valuation allowance could occur within the next 12 months upon resolution of the aforementioned uncertainties.

#### Year Ended December 31, 2006 (Restated) Compared to 2005 (Restated)

##### Revenues

Product sales were \$1,149.4 million in 2006 as compared with \$749.9 million in 2005, an increase of approximately 53%.

Sales of LUNESTA were \$565.4 million in 2006 as compared to \$327.1 million in 2005, an increase of approximately 73%. The increase is primarily the result of a 65% increase in the number of units sold, which is principally attributable to twelve months of sales in 2006 as compared to nine months of sales in 2005. The increase is also related to a 5% increase in net selling price, which resulted from a gross sale price increase of approximately 11%, offset by sales discounts and allowances. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales."

Sales of XOPENEX Inhalation Solution were \$543.0 million in 2006 as compared with \$410.8 million in 2005, an increase of approximately 32%. The increase is primarily due to a 13% increase in the number of units sold and a 17% increase in the net selling price per unit, which included a weighted average gross per unit price increase of approximately 8%. Adjustments recorded to gross sales are disclosed below under the heading "Analysis of gross sales to net sales."

Sales of XOPENEX HFA were \$41.0 million in 2006 as compared to \$12.0 million in 2005, an increase of approximately 243%. We introduced XOPENEX HFA commercially in December 2005 and our XOPENEX HFA revenues in 2005 relate primarily to initial inventory stocking by the wholesalers.

*Analysis of gross sales to net sales*—The following table presents the adjustments deducted from total gross sales to arrive at total net sales:

	For the Year Ended December 31,					
	2006 (as restated)(1)	% of Sales	2005 (as restated)(2)	% of Sales	Change	% Change
			(Dollars in Thousands)			
Gross sales . . . . .	\$1,435,363	100.0%	\$910,550	100.0%	\$524,813	58%
Adjustments to gross sales:						
Payment term discounts . .	29,264	2.0%	17,589	1.9%	11,675	66%
Wholesaler fee-for-service .	42,048	2.9%	15,817	1.7%	26,231	166%
Government rebates and contractual discounts . . .	190,206	13.3%	102,610	11.3%	87,596	85%
Returns . . . . .	20,255	1.4%	21,830	2.4%	(1,575)	(7)%
Other (includes product introduction discounts) .	4,216	0.3%	2,839	0.3%	1,377	49%
Sub-total adjustments . . . . .	285,989	19.9%	160,685	17.6%	125,304	78%
Net sales . . . . .	<u>\$1,149,374</u>	<u>80.1%</u>	<u>\$749,865</u>	<u>82.4%</u>	<u>\$399,509</u>	<u>53%</u>

(1) For 2006, as a result of the restatement, the dollar value of government rebates and contractual discounts increased by \$13.4 million and, as a percentage of net sales, increased from 12.3% to 13.3%.

(2) For 2005, as a result of the restatement, the dollar value of government rebates and contractual discounts increased by \$19.8 million and, as a percentage of net sales, increased from 9.1% to 11.3%.

The increase in adjustments to gross sales as a percentage of gross sales in 2006 as compared to 2005 primarily reflected an increase in government rebates and contractual discounts as a result of

(1) an increase in discounts we offered primarily on the sales XOPENEX HFA, which was commercially introduced in December 2005; (2) an increase in discounts offered to managed care organizations; and (3) an increase in discounts given through Medicare and Medicaid programs. Wholesaler fee-for-service discounts also increased in 2006 as compared to 2005, as these discounts did not commence until the second quarter of 2005. Offsetting these increases in adjustments to gross sales as a percentage of gross sales were (1) a decrease in government rebates and contractual discounts due to a reversal of reserves relating to rebates under the Department of Veterans Affairs TRICARE Pharmacy Benefits Program, which was based on a U.S. Federal Court of Appeals ruling in September 2006 that pharmaceutical manufacturers are not required to provide reimbursement for drugs purchased through the TRICARE Program; and (2) a decrease in sales returns primarily due to a decrease in actual returns for XOPENEX Inhalation Solution and the weighting of LUNESTA returns which are estimated at a lower rate.

Royalties were \$33.8 million in 2006 as compared with \$51.2 million in 2005, respectively, a decrease of approximately 34%. The decrease is primarily due to the decrease in royalties earned on the sales of ALLEGRA under our agreement with sanofi-aventis, which were \$16.6 million in 2006 as compared to \$36.9 million in 2005, primarily because we ceased to receive royalties on sales of ALLEGRA in the United States beginning in late 2005. Pursuant to the terms of our U.S. agreement with sanofi-aventis, our royalties on the sale of ALLEGRA in the United States, which have historically been between \$15 and \$20 million per year, terminated based on the introduction of a generic equivalent of this product in the United States in September 2005. We are still entitled to receive royalties on the sale of ALLEGRA outside of the United States in countries where we hold patents covering ALLEGRA and no generic equivalent product has been introduced.

Royalties earned on sales of CLARINEX under our agreement with Schering-Plough increased to \$12.2 million in 2006 from \$9.4 million in 2005. In August 2006, we were notified that several ANDAs containing Paragraph IV certifications had been received by the FDA seeking approval of generic versions of certain of Schering-Plough's CLARINEX products. If and while a generic version of a CLARINEX product is marketed in the United States without Schering-Plough's consent, Schering-Plough will have no obligation to pay royalties to us on the U.S. sales of CLARINEX products.

Royalties earned on sales of XYZAL/XUSAL under our agreement with UCB increased slightly to \$5.0 million in 2006, as compared to \$4.9 million in 2005.

#### *Costs of Revenues*

Cost of products sold was \$103.8 million in 2006 as compared with \$66.7 million in 2005, or approximately 7% of gross product sales for both 2006 and 2005.

Cost of LUNESTA sold as a percentage of LUNESTA gross sales was approximately 6% in 2006 and 2005, principally due to royalties we pay to a third party on net sales of LUNESTA.

Cost of XOPENEX Inhalation Solution sold as a percentage of XOPENEX Inhalation Solution gross sales was approximately 7% in 2006, as compared with 8% in 2005. The decrease in the cost as a percentage of gross sales is primarily due to a gross sales price increase in 2006.

Cost of XOPENEX HFA sold as a percentage of XOPENEX HFA gross sales was approximately 15% in 2006 compared to 11% in 2005. Included in the costs of XOPENEX HFA sold is a royalty paid on net sales of XOPENEX HFA to 3M, our third-party finished goods manufacturer of the product. We commercially introduced XOPENEX HFA in December 2005. The increase in the cost as a percentage of gross sales is primarily due to an increase in the cost of materials used in manufacturing.

Cost of royalties earned was \$976,000 for 2006, compared with \$749,000 in 2005. The cost of royalties in both periods relates to an obligation to a third party as a result of royalties we earn from Schering-Plough based on its sales of CLARINEX. This increase in obligations to the third party is due to the increase in royalties earned in 2006 as compared to 2005.

## Research and Development

Research and development expenses were \$163.5 million in 2006 as compared to \$144.5 million in 2005, an increase of approximately 13%. The increase is primarily due to our increased spending on two of our early-stage projects, SEP-225289 and SEP-227162, the LUNESTA Phase IIIB/IV projects, and drug discovery efforts. In addition, we experienced a \$15.0 million increase in non-project specific personnel-related expense, which includes stock-based compensation expense of \$11.0 million in 2006, resulting from our January 1, 2006 implementation of Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, (revised 2004), or SFAS 123(R), as compared to \$0 in 2005. Offsetting these increases to research and development expenses, was a reduction to project spending on XOPENEX HFA and BROVANA in 2006 as compared to 2005.

Below is a summary of development of our products and product candidates that represent 10% or more of our direct project research and development spending for the year ended December 31, 2006. The "Estimate of Completion of Phase" column contains forward-looking statements regarding expected timing of completion of product development phases. Completion of product development, if successful, culminates in the submission of an NDA to the FDA; however, there can be no assurance that the FDA will accept for filing, or approve, any NDA. The actual timing of completion of phases could differ materially from the estimates provided in the table. In the table below, the three FDA-approved products and two product candidates listed accounted for approximately 94% of our direct project research and development spending in 2006. No other product candidate accounted for more than 4% of our direct research and development spending in 2006.

Product or Product Candidate	Indication	Phase of Development	Estimate of Completion of Phase
LUNESTA (eszopiclone) . . . . .	Insomnia	*	*
XOPENEX HFA (levalbuterol tartrate) . . . .	Respiratory—Asthma	**	**
BROVANA (arformoterol tartrate) . . . . .	Respiratory—COPD	NDA Approved	***
SEP-225289 . . . . .	Depression	Phase I	2007
SEP-227162 . . . . .	Depression	Phase I	2007

\* We commercially introduced LUNESTA in April 2005; research and development spending in 2006 relates to Phase IV clinical studies.

\*\* We commercially introduced XOPENEX HFA in December 2005; research and development spending in 2006 relates to Phase IV clinical studies.

\*\*\* The FDA approved our BROVANA NDA in October 2006. We commercially introduced BROVANA in April 2007.

Below is a summary of expenditure information related to our products and product candidates representing 10% or more of our direct project research and development spending during the year ended December 31, 2006 and 2005, as well as the costs incurred to date on these projects. The costs in this analysis include only direct costs and do not include certain indirect labor, overhead, share-based

compensation, up-front license fees, milestone payments, or other costs that benefit multiple projects. As a result, fully-loaded research and development cost summaries by project are not presented.

	Project costs for the year ended December 31, 2006	Project costs through December 31, 2006	Project costs for the year ended December 31, 2005	Project costs through December 31, 2005
	(In Thousands)			
LUNESTA (eszopiclone) . . . . .	\$20,301	\$220,023	\$16,159	\$199,722
XOPENEX HFA (levalbuterol tartrate) . . . . .	12,507	169,298	24,094	156,791
BROVANA (arformoterol tartrate) . . . . .	12,353	173,931	18,059	161,578
SEP-225289 . . . . .	9,041	13,110	3,951	4,069
SEP-227162 . . . . .	6,394	8,140	1,746	1,746

#### *Selling, Marketing and Distribution*

Selling, marketing and distribution expenses were \$691.7 million in 2006 as compared with \$585.8 million in 2005, an increase of approximately 18%. The increase is primarily related to a \$43.3 million increase in personnel-related expense, which included 1) an increase in salaries as a result of hiring additional sales representatives and management to support marketed products and 2) an increase in stock-based compensation expense of \$15.2 million in 2006 over 2005, as a result of our January 1, 2006 implementation of SFAS 123(R), which were offset by a decrease in commission expense as a result of lower commission level achievement in 2006 as compared to 2005. In addition to the personnel-related expense increase, we incurred a \$27.0 million increase in marketing, advertising and promotion costs primarily in support of LUNESTA.

#### *General and Administrative*

General and administrative costs were \$72.1 million in 2006 as compared with \$40.8 million in 2005, an increase of approximately 77%. The increase is largely due to a \$22.8 million increase in personnel-related costs, which is primarily attributable to a \$17.5 million increase in stock-based compensation expense over 2005 as a result of our January 1, 2006 implementation of SFAS 123(R). The increase was also partly due to a \$16.5 million increase in legal fees related to patent support and litigation and shareholder lawsuit-related costs, as well as expense associated with responding to the SEC's informal inquiry into our stock option grants and practices and the related internal investigation.

#### *Other Income (Expense)*

Interest income was \$46.6 million in 2006 as compared to \$27.5 million in 2005, an increase of approximately 70%. The increase is due to higher average balances of cash and short- and long-term investments combined with an increase in the interest rates earned on investments in 2006. Our monthly average cash and investment balance was approximately \$990.2 million and \$868.6 million for the years ended December 31, 2006 and 2005, respectively. For 2006 and 2005, the average annualized interest rate that we earned on our investments was 4.7% and 3.2%, respectively.

Interest expense was \$22.2 million in 2006 as compared with \$23.4 million in 2005. The expense in both periods is primarily related to the interest we paid on our 5% convertible subordinated debentures due 2007, which were paid in full in February 2007.

Equity in investee losses were \$422,000 in 2006 as compared with \$665,000 in 2005. The equity in investee loss in 2006 and 2005 represents our portion of the losses of BioSphere Medical, Inc.

Gain on sale of equity investment was \$0 in 2006 as compared with \$18.3 million in 2005. The gain in 2005 represents the gain we recorded when we received cash in exchange for our shares of Vicuron Pharmaceuticals, Inc., or Vicuron, in connection with the merger of Pfizer and Vicuron in September 2005.

## *Income Taxes*

Income tax expense was \$3.7 million in 2006 as compared to \$151,000 in 2005. Income tax expense in 2006 includes Federal and state AMT expense. Income tax expense in 2005 includes state tax expense and foreign income tax expense. Fiscal year 2006 was the first time we generated income from operations and, therefore we will continue to maintain a full valuation allowance on our deferred tax assets until profitability has been sustained over an appropriate time period and in amounts that are sufficient to support a conclusion that it is more likely than not that a portion or all of the deferred tax assets will be realized. If we determine, based on future profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods.

## **Critical Accounting Policies**

In December 2001, the SEC requested that all registrants discuss their most “critical accounting policies” in management’s discussion and analysis of financial condition and results of operations. The SEC indicated that a “critical accounting policy” is one which is both important to the portrayal of a company’s financial condition and results and requires management’s most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. While our significant accounting policies are more fully described in Note B to our consolidated financial statements included in this report, we believe the following accounting policies are critical:

**Product Revenue Recognition:** We recognize revenue from product sales, upon delivery, when title to product and associated risk of loss has passed to the customer and collectability is reasonably assured. We record revenues from product sales net of applicable allowances for returns, rebates and other applicable discounts and allowances.

The timing of product shipments and receipts can have a significant impact on the amount of revenue recognized in a period. Also, the majority of our products are sold through distributors. Revenue could be adversely affected if distributor inventories increased to an excessive level. If this were to happen, we could experience reduced purchases in subsequent periods, or product returns from the distribution channel due to overstocking, low end-user demand or product expiration. We have invested in resources to track channel inventories in order to prevent distributor inventories from increasing to excessive levels. If we determine that distributor inventories are at excessive levels, we do not recognize revenue for those shipments that we believe represent excessive inventory.

**Revenue Recognition, Multiple Element Arrangements—**We have entered into collaborative agreements with other pharmaceutical companies for the development and commercialization of our eszopiclone product outside of the United States, Canada and Mexico. These agreements are in the form of license agreements that call for nonrefundable upfront payments, milestone payments on achieving significant milestones, and royalty payments on sales if and when the compound receives marketing approval.

Our revenue recognition policy for all multiple revenue-generating arrangements are in accordance with the guidance provided in the SEC’s Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

**Royalty Revenue Recognition:** Royalty revenue is recognized based upon estimates of sales in licensed territories in the period in which the sales occur. These estimates are derived when possible from information from the company paying the royalty, or from historical data and third-party prescription data. Changes in market conditions, such as the introduction of competitive products, can lead to significant deviations from historical patterns and therefore cause estimates to be inaccurate. When estimates differ from actual results, the difference is recognized in the following quarter,

provided the difference is not material to the results of either quarter. Historically, our estimates have not materially differed from our actual results.

**Product Sales Allowances and Reserves:** We record product sales net of the following significant categories of product sales allowances: payment term discounts, wholesaler fee-for-service discounts, government rebates and contractual discounts (includes Medicaid discounts, Medicare discounts, managed care discounts, chargebacks and group purchasing organization, or GPO, contract discounts), returns and other discounts. Calculating each of these items involves significant estimates and judgments and requires us to use information from external sources. Based on known market events and trends, internal and external historical trends, third party data, customer buying patterns and up-to-date knowledge of contractual and statutory requirements, we are able to make reasonable estimates of sales discounts.

1) *Payment Term Discounts*—We offer our direct purchase customers a 2% prompt-pay cash discount as an incentive to remit payment within the first thirty days after the date of the invoice. Prompt-pay discount calculations are based on the gross amount of each invoice. We account for these discounts by reducing sales by the 2% discount amount when product is sold, and apply earned cash discounts at the time of payment. Since we began selling our products commercially in 1999, our customers have routinely taken advantage of this discount. Based on common industry practices and our customers' overall payment performance, we accrue for cash discounts on product sales recorded during the period. We adjust the accrual to reflect actual experience as necessary, and historical adjustments have not been material. Based on our history of estimating payment term discounts and the low dollar exposure, we do not anticipate that changes to estimates will have a material impact on net sales.

2) *Wholesaler Fee-for-Service Discounts*—In both 2007 and 2006, we entered into agreements with certain wholesaler customers that provide these wholesalers with the opportunity to earn discounts in exchange for the performance of certain services. Our effective rate of wholesaler fee-for-service discounts applied across all product gross sales in 2007 was approximately 1.8% as compared to 2.9% in 2006. Our accruals for wholesaler fee-for-service discounts are based on actual data of product sales made to wholesale customers with agreements and not on estimates. If the percentage of gross sales sold to wholesalers with agreements increases, our liability related to these discounts could increase materially.

3) *Government Rebates and Contractual Discounts*—

*Medicaid Discounts*—We record accruals for rebates to be provided through the Medicaid Drug Rebate Program as a reduction of sales when the product is sold. We rebate individual states for all eligible units purchased under the Medicaid program based on a rebate per unit calculation, which is driven off of our Average Manufacturer Price, or AMP. We estimate the expected rebate per unit to be used and adjust our rebate accruals based on expected changes in rebate pricing. We also examine the historical rebate trends and the trend of sales that become eligible for Medicaid programs and any changes expected to these trends. In addition, certain states have supplemental rebate programs, which provide such states with an additional rebate. Supplemental rebates, like rebates under the Medicaid Drug Rebate Program, are recorded as a reduction of sales when the product is sold. Rebate amounts are generally invoiced quarterly in arrears and paid thirty days after they are invoiced. As a result, our accrual consists of: (i) an estimate of the amount expected to be incurred for the current quarter's prescriptions; (ii) an accrual for prior quarters' unpaid rebates; and (iii) an accrual for estimated inventory in the distribution channel.

We recorded a provision for Medicaid rebates of 9.1% and 6.1% of gross sales in 2007 and 2006, respectively. The increase is attributable to an increase in Medicaid discounts that we offered on the sales of XOPENEX Inhalation Solution, LUNESTA, and XOPENEX HFA. The increase is also the result of a Medicaid reserve reversal in 2006 relating to a 2005 estimate. Actual Medicaid discounts could exceed historical experience and our estimates of expected Medicaid activity and rebate-per-unit



amounts. The most significant estimate we make in connection with this accrual is the estimate of the number of Medicaid-eligible units in the distribution channel. With the exception of the best price matters described in more detail in the "Explanatory Note" to this report on Form 10-K and notes to our consolidated financial statements included herein, our estimates have been approximately 90% accurate in recent quarters. Although the actual Medicaid rebate may vary by more than -10% of the estimated eligible Medicaid units in future periods, we believe, based on prior experience, a -10% variation in our estimate is reasonably likely. A 10% understatement of Medicaid-eligible units at December 31, 2007 would have resulted in an additional provision of approximately \$4.4 million.

*Medicare Discounts—Part B*—We record accruals for rebates to be provided through Medicare Part B programs, as a reduction of sales when the product is sold. We established a Medicare Part B rebate program in order to increase the access by Medicare Part B beneficiaries to our XOPENEX Inhalation Solution product through Medicare Part B pharmacy providers, or MPPs. We estimate the expected rebate using historical data and by examining trends and expected changes in Medicare Part B codes. Medicare Part B payments are paid to MPPs primarily on a monthly basis. Accordingly, the provision typically relates to the activity over a one-month period and, as a result, the total provision consists of: (i) an estimate of the amount expected to be incurred for the current month's prescriptions; (ii) an accrual for prior months' unpaid rebates; and (iii) an accrual for estimated inventory in the distribution channel.

*Medicare Discounts—Part D*—Effective January 1, 2006, Medicare created a prescription drug benefit for its beneficiaries known as Medicare Part D. The CMS contracted with numerous health plans and prescription drug benefit plans to design and administer the drug benefit, including the development of a formulary (which defines which products are covered and at what co-pay level). We pay rebates to certain Medicare Part D health plans and prescription drug plans on the utilization of LUNESTA, XOPENEX Inhalation Solution, XOPENEX HFA and BROVANA. XOPENEX Inhalation Solution has been, and we expect that it will remain, subject to reimbursement under Medicare Part B resulting in minimal Medicare Part D utilization. Our accruals for Medicare Part D are estimated based on projected sales volumes through the contracted health and drug plans.

The provision for both Medicare rebates was 4.9% of gross sales in 2007 and 1.4% in 2006. Actual Medicare discounts could change significantly in the future based on future Medicare reimbursement classifications.

Medicare rebates at our current reimbursement levels represent an immaterial amount of sales rebates. Based on the accuracy of estimates and the small dollar amounts involved, we do not expect changes in estimates to have a material impact on net sales.

*Managed Care Discounts*—We have entered into agreements with certain MCOs whereby we provide agreed upon discounts to such entities based on the achievement of sales volume and/or market share purchasing targets. We record accruals for these discounts as a reduction of sales when product is sold based on discount rates and expected levels of sales volumes of these MCOs during a period. We estimate eligible sales based on historical amounts and sales trends and expected changes to these trends. Discounts are generally invoiced and paid quarterly in arrears. Accordingly, our accrual consists of: (i) the amount expected to be incurred for the current quarter's prescriptions, (ii) an accrual for prior quarters unpaid discounts; and (iii) an accrual for estimated inventory in the distribution channel.

The provision for MCO rebates was approximately 3.3% and 1.7% of gross sales in 2007 and 2006, respectively. Actual MCO discounts could exceed historical experience and our estimates of expected future participation in these programs. However, in part due to the fact that only a few organizations currently account for approximately 90% of our MCO discounts, our MCO discount estimates have historically been very similar to the actual MCO discounts. We expect that a small number of organizations will continue to account for substantially all of our MCO discounts for the foreseeable

future and, therefore, do not expect significant changes to our MCO discount estimates in future periods.

*Chargebacks and GPO Contract Discounts*—We have entered into agreements with certain GPOs in which their members can purchase product from our wholesalers at a specified price. GPOs are organizations that represent a group of end buyers in the purchase of goods. These agreements involve the wholesalers who receive a stated margin on sales to GPOs. When the difference between the wholesaler's purchase price and the GPO's price creates a margin less than the amount agreed between us and the wholesaler, the wholesaler requests a credit, which is referred to as a chargeback. We record accruals for these discounts as a reduction of sales when product is sold. We estimate eligible sales based on a history of the average actual chargebacks and an average of the chargeback cycle time, which is the time from when a wholesaler sells to a GPO until we issue a credit to the wholesaler. We examine the history of sales which qualify for chargebacks and monitor sales trends and contractual changes. Our accrual consists of the amount expected to be incurred for the current sales in the calculated chargeback cycle, plus an accrual for estimated inventory in the distribution channel.

The provision for chargebacks and GPO contract credits was approximately 2.4% and 4.5% of gross sales in 2007 and 2006, respectively. The decrease is primarily due to a decrease in XOPENEX HFA units sold under a government contract with the Veterans Administration in 2007 as compared to 2006. Actual chargeback and GPO contract credits could exceed historical experience and our estimates of future participation in these programs. However, over the past few years, chargeback activity has been fairly stable with the exception of XOPENEX HFA, which currently has a limited number of chargeback contracts. Therefore, we do not expect significant variation between actual chargeback and GPO credits and our estimates.

4) *Returns*—Customers can return short-dated or expired product that meets the guidelines set forth in our returned goods policy. Product shelf-life from the date of manufacture for XOPENEX Inhalation Solution is 15 months, XOPENEX HFA is 21 months, LUNESTA is 15-24 months and BROVANA is 18 months. Returns are accepted from wholesalers and retail pharmacies. Customers can return product with six months or less of shelf life remaining and expired product within twelve months following the expiration date. We record an estimate for returns as reductions of revenue at the time product sales are recorded. We base our estimates of product returns on the percentage of returns that we have experienced historically, on a historical aging of the average time a return occurs from the time the product was sold and on key analytical measures such as the percentage of the outstanding pipeline covered by the returns reserve. For products with insufficient return history, we estimate by examining data of similar drugs. For example, with LUNESTA, we researched industry data on return patterns of widely prescribed insomnia drugs. We may adjust our estimate of product returns if we are aware of other factors that we believe could significantly impact our expected return percentages. These factors include our estimate of inventory levels of our products in the distribution channel, the product shelf-life of the product we have shipped, competitive issues such as new product entrants and other known changes in sales trends.

The provision for returns was approximately 1.9% and 1.4% in 2007 and 2006, respectively. The increase in return percentage provision in 2007 from 2006 is primarily due to a higher rate of return of XOPENEX Inhalation Solution as a result CMS' decision to discontinue the stand-alone reimbursement for the product and also higher returns of LUNESTA, primarily in the 1mg tablets and all hospital units doses. Actual returns could exceed historical experience and our estimates of expected future returns due to factors such as wholesaler and retailer stocking patterns and inventory levels and/or competitive changes. Based on these factors, and as a result of fluctuations observed in prior periods, we believe it is reasonably likely that the actual returns provision percentage could vary from the estimated percentage within a range of up to 0.25%. If the returns provision percentage for each of these products had increased by 0.25% of gross sales in 2007, an additional provision of approximately \$4.0 million would have been necessary.

Many of our accruals include an estimate of inventory in the distribution pipeline. At December 31, 2007, we believe a reasonable estimate of the value of our pipeline inventory in gross sales dollars is approximately \$103.6 million for XOPENEX Inhalation Solution, \$17.9 million for XOPENEX HFA, \$108.6 million for LUNESTA and \$2.4 million for BROVANA.

5) *Other Discounts*—At times we offer special programs and discounts. In 2007, we implemented a patient assistance program, which provides all our products at no cost to those eligible patients who lack prescription drug coverage and are unable to afford them. In 2007 and 2006, we utilized discount programs related to LUNESTA and XOPENEX HFA to support the goal of making the products widely available. In 2007, our coupon and voucher utilization increased as compared to 2006, which is largely the result of an increase in our coupon programs related to XOPENEX HFA. These programs include coupons and vouchers, including the LUNESTA 7-Night Challenge introduced in September 2006. Under the coupon program, physicians give patients coupons to purchase the prescribed drug at a discount from any retail pharmacy. We reimburse retail pharmacies for these discounts through a third-party administrator. Under the voucher and LUNESTA 7-Night Challenge programs, physicians give patients vouchers to obtain free samples of the prescribed drug from any retail pharmacy. We reimburse retail pharmacies for the cost of these products through a third-party administrator. We use the voucher program primarily in states where samples cannot be shipped directly to physicians.

In each case mentioned above, we estimate the cost of reimbursement as a reduction of gross sales when the product is sold. In addition, we maintain an accrual for unused coupons and vouchers based on outstanding total coupons and vouchers and their historical usage rates and adjust this accrual whenever changes in such historical usage rate occurs. Each of these programs has a defined expiration date.

The following table summarizes activity in each of the above product sales allowances and reserve categories for the years ended December 31, 2007 and 2006:

	Payment Terms Discount	Wholesaler Fee for Service	Government Rebates and Contractual Discounts	Returns	Other Discounts	Total
	(In Thousands)					
<b>Balance at December 31, 2005</b>						
(as restated) .....	\$ (2,632)	\$ (9,503)	\$ (86,045)	\$(16,268)	\$ (552)	\$(115,000)
Current provision:						
Current year .....	(29,264)	(42,048)	(199,791)	(20,255)	(4,236)	(295,594)
Prior year .....	—	—	9,585	—	20	9,605
Total .....	<u>(29,264)</u>	<u>(42,048)</u>	<u>(190,206)</u>	<u>(20,255)</u>	<u>(4,216)</u>	<u>(285,989)</u>
Actual:						
Current year .....	24,587	25,567	111,876	1,383	2,660	166,073
Prior year .....	2,958	9,315	38,142	11,922	597	62,934
Total .....	<u>27,545</u>	<u>34,882</u>	<u>150,018</u>	<u>13,305</u>	<u>3,257</u>	<u>229,007</u>
<b>Balance at December 31, 2006</b>						
(as restated) .....	\$ (4,351)	\$(16,669)	\$(126,233)	\$(23,218)	\$ (1,511)	\$(171,982)
Current provision:						
Current year .....	(31,939)	(29,086)	(312,049)	(29,606)	(14,791)	(417,471)
Prior year .....	—	457	(637)	—	440	260
Total .....	<u>(31,939)</u>	<u>(28,629)</u>	<u>(312,686)</u>	<u>(29,606)</u>	<u>(14,351)</u>	<u>(417,211)</u>
Actual:						
Current year .....	27,773	19,063	175,373	2,142	12,629	236,980
Prior year .....	4,378	14,123	56,813	26,331	590	102,235
Total .....	<u>32,151</u>	<u>33,186</u>	<u>232,186</u>	<u>28,473</u>	<u>13,219</u>	<u>339,215</u>
<b>Balance at December 31, 2007 ...</b>	<u>\$ (4,139)</u>	<u>\$(12,112)</u>	<u>\$(206,733)</u>	<u>\$(24,351)</u>	<u>\$ (2,643)</u>	<u>\$(249,978)</u>

**Cash and Cash Equivalents:** Cash equivalents are highly liquid, temporary cash investments having original maturity dates of three months or less.

**Short- and Long-Term Investments:** Short and long-term investments include U.S. government securities, certificates of deposit, corporate commercial paper, corporate bonds, asset-backed securities, equity securities and auction rate securities. Those investments with a maturity of less than one year are classified as short-term. Short- and long-term investments are classified as either “available-for-sale” or “held-to-maturity”. At acquisition, we designate the appropriate classification of the investment purchased based upon its intended holding period. At each reporting date, the appropriateness of the classification is reassessed. Although auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than ninety days, the contractual maturities can be well in excess of ten years, and are therefore classified as, long-term investments. Available-for-sale investments are carried at fair market value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss). Realized gains and losses for securities classified as available-for-sale are included in earnings and are derived using the specific identification method for determining the cost of securities sold. Held-to-maturity investments are recorded at cost plus accrued amortization, which approximates fair value. We evaluate our investments for possible other-than-temporary impairment by reviewing factors such as the investment rating for the securities, the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value. If it is determined that a decline in value is other-than-temporary an impairment charge is recorded to the extent that the carrying value of the security exceeds the estimated fair market value.

**Accounts Receivable and Bad Debt:** Our trade receivables in 2007 and 2006 primarily represent amounts due to us from wholesalers, distributors and retailers of our pharmaceutical products. We perform ongoing credit evaluations of our customers and generally do not require collateral. Bad debt write-offs were not significant in 2007, 2006 and 2005; however, they could be significant in the future and we monitor our receivables closely because a few customers make up a large portion of our overall revenues. In both 2007 and 2006, our top four customers accounted for approximately 87% respectively, of our total revenues.

**Amortization, Depreciation and Certain Long-Lived Assets:** Long-lived assets include:

- **Property and Equipment**—Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operations. On disposal, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations as other income (expense). Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computers and software, which are recorded in office equipment, have estimated useful lives of three years. All laboratory, manufacturing and office equipment have estimated useful lives of three to ten years. Buildings have an estimated useful life of 30 years. Leasehold improvements are amortized over the shorter of the estimated useful lives of the improvements or the remaining term of the lease.
- **Deferred Financing Costs**—Deferred financing costs relating to expenses incurred to complete convertible subordinated debt offerings are amortized evenly over the earlier of the term of the debt, or the date on which we can first be obligated to repurchase all or part of the debt.

**Income Taxes:** Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are

expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. The possible adverse impact to our XOPENEX Inhalation Solution sales if an "at risk" generic launch were to occur or we are unable to successfully defend our patent rights and increased sales and marketing expenses as a result of the expected commercial introduction of OMNARIS AQ in the first half of 2008 and the expected commercial introduction ALVESCO HFA in the second half of 2008, management continues to conclude a valuation allowance is required for the full amount of the deferred tax asset. Of our total valuation allowance of \$662.1 million, approximately \$152.2 million relates to stock option compensation deductions. The tax benefit associated with the stock option compensation deductions will be credited to equity if realized. If in the future, we determine based on expected profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods. Such release of the valuation allowance could occur within the next 12 months upon resolution of the aforementioned uncertainties.

We account for uncertain tax positions in accordance with FASB Interpretation No. 48, *Accounting for Uncertainty in Income Taxes—an Interpretation of FASB Statement No. 109*, or FIN 48. FIN 48 prescribes a recognition threshold and measurement attribute for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return and also provides guidance on various related matters such as derecognition, interest and penalties, and disclosure. We also recognize interest and penalties, if any, related to unrecognized tax benefits in income tax expense.

**Inventory Write-Downs:** Inventory represents bulk material, work-in-process and finished goods relating to our commercial products on hand, valued at lower of cost or market value. Inventories are reviewed periodically for slow-moving or obsolete status based on sales activity, both projected and historical, and through a review of the expiration dates. Our current sales projections provide for full utilization of the inventory balance. If product sales levels differ from projections, inventory may not be fully utilized and could be subject to impairment, at which point we would write down the value of the inventory to its net realizable value.

We expense costs relating to inventory as research and development expense until such time as we receive an approval letter from the FDA for a new product, and then we begin to capitalize the inventory costs relating to that product.

**Share-Based Compensation**—Effective January 1, 2006, we adopted the provisions of SFAS 123(R), which resulted in changes to our financial statements as detailed in Note B and Note O to the financial statements. Determining the amount and distribution of expense for stock-based compensation, as well as the associated impact to the balance sheets and statements of cash flows, requires us to develop estimates of the fair value of stock-based compensation expense.

We estimate the fair value of stock options using the Black-Scholes valuation model. This valuation model takes into account the exercise price of the award, as well as a variety of assumptions. These assumptions used to estimate the fair value of stock options include the expected term, the expected volatility of our stock over the expected term, the risk-free interest rate over the expected term, and our expected annual dividend yield. Prior to our adoption of SFAS 123(R), we based the expected volatility of our stock on the historical price of our common stock. Upon our adoption of SFAS 123(R) in January 2006, we began utilizing implied volatility, derived from our traded options, to determine the volatility of our stock. As required by SFAS 123(R), management has also made an estimate of expected forfeitures in determining the amount of expense to be recorded, and is recognizing compensation expense only for those equity awards expected to vest. We believe that the valuation technique and the approach utilized to develop the underlying assumptions are appropriate in

calculating the fair value of stock-based compensation expenses. These estimates are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

**Research and Development Expenses:** We expense internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred. We also expense the cost of purchased technology in the period of purchase if we believe that the technology has not demonstrated technological feasibility and that it does not have an alternative future use.

### **Recent Accounting Pronouncements**

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51*, or SFAS 160. SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. This pronouncement will be effective for fiscal years beginning on or after December 15, 2008. SFAS 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS 160 shall be applied prospectively. We do not expect the adoption of SFAS 160 to have a material impact on our consolidated financial statements.

In December 2007, the Emerging Issues Task Force of the FASB, or EITF, reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, or EITF 99-19, and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms of the arrangement, the nature of the entity's business, and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-1 to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, which will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. SFAS No. 141(R) is effective for transactions occurring on or after January 1, 2009. We are evaluating the impact this standard will have on our financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159, which allows entities the option to measure eligible financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS 159 to have a material impact on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. On November 14, 2007, the FASB agreed to a one-year deferral for the implementation of SFAS 157 for other non-financial assets and liabilities. We do not expect the adoption of SFAS 157 to have a material impact on any non-financial assets and liabilities or on our consolidated financial statements.

### **Liquidity and Capital Resources**

Our liquidity requirements have historically consisted of research and development expenses, sales and marketing expenses, capital expenditures, working capital, debt service and general corporate expenses. Historically, we have funded these requirements and the growth of our business primarily through convertible subordinated debt offerings, the issuance of common stock, including the exercise of stock options, sales of our products and license agreements for our drug compounds. We now expect to fund our liquidity requirements primarily with revenue generated from product sales. We also believe we have the ability to meet our short-term liquidity needs through the use of our cash and short-term investments on hand at December 31, 2007.

Cash, cash equivalents and short- and long-term investments totaled \$1.1 billion, or 76% of total assets at December 31, 2007, compared to \$1.2 billion, or 78% of total assets, at December 31, 2006. At December 31, 2007, our portfolio included \$99.9 million invested in highly-rated (AAA) student-loan-backed auction rate securities, of which some are associated with failed auctions in 2008. The funds associated with our auction rate securities that have failed auction may not be accessible until a successful auction occurs, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured.

Net cash provided by operating activities for the year ended December 31, 2007 was \$324.0 million, which includes net income of \$58.3 million. Our net income includes non-cash charges of \$53.5 million, consisting primarily of share-based compensation and depreciation and amortization expense. Accounts receivable decreased by \$15.5 million primarily due to LUNESTA and XOPENEX Inhalation Solution sales. Inventory increased by \$14.7 million primarily due to an effort to increase the number of days of on hand inventory of XOPENEX HFA. Other assets increased by \$1.5 million primarily due to an increase in prepaid expenses and royalty receivables off-set by a decline in interest receivable. Accounts payable increased by \$6.5 million primarily due to timing of vendor payments. Accrued expenses increased by \$96.8 million primarily due to (1) the recording of the \$75.0 million upfront payment we paid to Bial in January 2008, (2) increased accrued sales and marketing and accrued research and development expenses as a result of timing of vendor payments, and (3) a decline in accrued interest as a result of the February 2007 payment in full of our 5% convertible subordinated debentures. Other liabilities increased by \$6.7 million primarily due to accruals associated with the restructuring and realignment of our sales force. Product sales allowances and reserves increased \$78.2 million primarily due to product revenue rebates related to LUNESTA and XOPENEX Inhalation Solutions product sales. Deferred revenue increased \$24.7 million primarily relating to licensing agreements with Eisai and GSK.

Net cash provided by investing activities for the year ended December 31, 2007 was \$263.8 million. As a result of liquidating certain securities into cash and cash equivalents, cash provided by net sales of short- and long-term investments was \$289.0 million. We made purchases of property and equipment of \$25.4 million and received proceeds from sales of equipment of \$273,000.

Net cash used in financing activities for the year ended December 31, 2007 was \$404.9 million. We received proceeds of \$36.1 million from issuing common stock upon the exercise of stock options issued

under our stock option plans. We also used \$441.2 million to repay capital lease obligations and long-term debt.

We believe our existing cash, cash equivalents, and short-term investments and the cash flow we anticipate from operations and current strategic alliances will be sufficient to support existing operations through at least the end of 2009. In the longer term, we expect to continue to fund our operations with revenue generated from product sales. Our actual future cash requirements and our ability to generate revenue, however, will depend on many factors, including:

- LUNESTA sales;
- XOPENEX Inhalation Solution and XOPENEX HFA sales;
- BROVANA sales;
- successful commercialization of OMNARIS AQ and ALVESCO HFA;
- successful acquisition of technologies, product candidates, approved products and/or businesses;
- successful expansion into foreign markets;
- our ability to establish and maintain additional strategic alliances and licensing arrangements;
- whether our debt, particularly debt due in 2008, will be paid in cash rather than converted into common stock pursuant to the terms of such debt;
- progress of our preclinical and clinical research programs and the number and breadth of these programs;
- progress of our development efforts and the development efforts of our strategic partners;
- achievement of milestones under our strategic alliance arrangements;
- royalties from agreements with parties to which we have licensed our technology; and
- the outcome of pending litigation, including litigation related to generic competition and/or any possible future litigation or the “at risk” launch of generic versions of our product.

If our assumptions underlying our beliefs regarding future revenues and expenses change, or if unexpected opportunities or needs arise, we may seek to raise additional cash by selling debt or equity securities or borrowing money from a bank. However, we may not be able to raise such funds on favorable terms, or at all.

Based on our current operating plan, we believe that we will not be required to raise additional capital to fund the repayment of our outstanding convertible debt when due, however we may choose to do so. If we are not able to successfully grow our revenue and properly manage our expenses, it is likely that our business would be materially and adversely affected and that we would be required to raise additional funds in order to repay our outstanding convertible debt. We cannot assure that, if required, we would be able to raise the additional funds on favorable terms, if at all.

#### *Acquisition Strategy*

In January 2008, we entered into an agreement with Nycomed for the exclusive U.S. distribution, development and commercialization in the United States, its territories and possessions of Nycomed's compound ciclesonide, and products incorporating such compound. In December 2007, we entered into a license agreement with Bial for the development and commercialization in the United States and Canada of Bial's anti-epileptic compound, BIA 2-093, which we now refer to as SEP-0002093. We paid Nycomed an upfront payment of \$150.0 million in February 2008 and may be required to make subsequent payments of up to \$280.0 million over the life of the agreement upon accomplishment of



various development and sales milestones. We paid Bial an upfront payment of \$75.0 million and are required to make subsequent payments upon accomplishment of various development and regulatory milestones, which could include up to an additional \$100.0 million if all milestones are met. We utilized cash in early 2008 to make the upfront payments to Nycomed and Bial.

As part of our business strategy, we plan to continue to consider and, as appropriate, make acquisitions of other businesses, approved products, product candidates and/or technologies. Our cash reserves and other liquid assets may be inadequate to consummate these acquisitions and it may be necessary for us to raise substantial additional funds and/or issue shares of our capital stock in the future to consummate these transactions. In addition, as a result of our acquisition efforts, we are likely to experience significant charges to earnings for acquisitions and related expenses (whether or not our efforts are successful) that may include transaction costs, closing costs or acquired in-process research and development charges.

#### *Convertible Subordinated Debt*

In February 2007, we paid in full \$440.0 million of outstanding 5% convertible debentures, which matured on February 15, 2007, plus approximately \$11.0 million in accrued interest. The \$440.0 million of 5% debentures were convertible into our common stock, at the option of the holder, at a price of \$92.38 per share, and the 5% interest was paid semi-annually, commencing on August 15, 2000. As part of the sale of the 5% debentures, we incurred approximately \$14.0 million of offering costs, which were recorded as intangible assets and were amortized over seven years, the term of the 5% debentures.

In January 2004 and December 2003, we issued an aggregate of \$750.0 million in principal amount of 0% convertible senior subordinated notes including \$250.0 million principal amount of 0% Series A convertible senior subordinated notes due 2008, or Series A notes, due 2008, and \$500.0 million principal amount of 0% Series B convertible senior subordinated notes due 2010, or Series B notes due 2010. Note holders may convert the Series A notes due 2008 into shares of our common stock at a conversion price of \$31.89 per share and the Series B notes due 2010 into shares of our common stock at a conversion price of \$29.84 per share. In each case, the conversion price is subject to adjustment, at any time before close of business on December 15, 2008, in the case of the 0% Series A notes due 2008, or December 15, 2010, in the case of the 0% Series B notes due 2010. We may not redeem the notes prior to maturity. The net proceeds to us after offering costs were approximately \$728.9 million. During September 2004, certain holders of our 0% Series A notes due 2008 and 0% Series B notes due 2010, agreed, in separately negotiated transactions, to convert \$177.2 million and \$352.0 million in aggregate principal amount of their 0% Series A notes due 2008 and 0% Series B notes due 2010, respectively, into an aggregate of 5,556,104 and 11,797,483 shares of our common stock, respectively. As an inducement to convert their notes, we paid the holders of the 0% Series A notes due 2008 and 0% Series B notes due 2010 aggregate cash payments of \$23.9 million and \$45.9 million, respectively. At December 31, 2007, \$72.8 million and \$148.0 million of the 0% Series A notes due 2008 and 0% Series B notes due 2010, respectively, remained outstanding.

In December 2003, we used approximately \$94.8 million of the proceeds from the issuance of 0% Series A convertible senior subordinated notes due 2008 and 0% Series B convertible senior subordinated notes due 2010 to purchase four series of call spread options on our common stock expiring at various dates between May 12, 2004 and December 9, 2005. The call spread options, which are now completed, could have been settled at our option in either net shares or in cash. During the second and fourth quarters of 2004, we settled series one and two for cash resulting in payments to us in the amount of \$124.3 million. The first series of settled options expired at various dates beginning on May 12, 2004 and ending on June 9, 2004 and the second series of options expired at various dates beginning on November 11, 2004 and ending on December 9, 2004. During the second quarter of 2005, the third series of settled options expired at various dates beginning on May 12, 2005 and ending on June 9, 2005. We settled the third series for cash resulting in a payment to us in the amount of \$123.8 million. In the fourth quarter of 2005, the fourth and final series expired in equal installments on each business day from November 11, 2005 through December 9, 2005. We elected to settle the fourth series in net shares for which we received 2,326,263 shares of our common stock, which we currently hold as treasury stock.

In September 2004, we issued \$500.0 million in principal amount of 0% convertible senior subordinated notes due 2024, or 0% notes due 2024. The 0% notes due 2024 are convertible, at the option of the holder upon certain specified circumstances, into cash and, if applicable, shares of our common stock at an initial price of \$67.20 per share, subject to adjustment. The note holders may, at their election, require us to repurchase for cash all or part of the notes on October 15, 2009, 2014 and 2019 at a purchase price equal to 100% of the principal amount of any notes repurchased. We may also be required to repurchase for cash all or part of the notes upon a change in control or if our stock is no longer traded on NASDAQ or a similar market at a purchase price equal to 100% of the principal amount of any notes repurchased, plus in certain change in control circumstances an additional make-whole payment. On or after October 20, 2009, we have the option to redeem for cash all or part of the notes at any time at a redemption price equal to 100% of the principal amount of the notes redeemed.

In order to reduce future cash interest payments, as well as future payments due at maturity, we may, from time to time, depending on market conditions, repurchase additional outstanding convertible debt for cash, exchange debt for shares of our common stock, warrants, preferred stock, debt or other considerations, or otherwise extinguish debt through a combination of any of the foregoing. If we exchange shares of our capital stock, or securities convertible into or exercisable for our capital stock, for outstanding convertible debt, the number of shares that we might issue as a result of such exchanges could significantly exceed the number of shares originally issuable upon conversion of such debt and, accordingly, such exchanges could result in material dilution to holders of our common stock. We cannot assure you that we will repurchase or exchange any additional outstanding convertible debt.

### *BioSphere*

BioSphere was a consolidated subsidiary from 1994 through July 2, 2001. As a result of a public offering of BioSphere common stock in 2001, our ownership of BioSphere was reduced from approximately 55% to 26%. Therefore, effective July 3, 2001, we changed the method of accounting for our investment in BioSphere from consolidating the results of BioSphere operations to the equity method. On November 10, 2004, we purchased, in a private placement, 4,000 shares of BioSphere Series A Convertible Preferred Stock and warrants to purchase an additional 200,000 shares of BioSphere common stock from BioSphere for an aggregate purchase price of \$4.0 million. Each share of BioSphere Series A Convertible Preferred Stock is convertible into 250 shares of BioSphere common stock. In addition, quarterly dividends of 6% per annum are paid on the shares in either cash or additional shares of Series A Convertible Preferred Stock, at BioSphere's election and, as of December 31, 2007, we had acquired an additional 749 shares of Series A Convertible Preferred Stock in connection with dividend payments.

At December 31, 2007 and 2006, we owned 3,224,333 shares, or approximately 18% of BioSphere's outstanding common stock. The fair market value of those shares was approximately \$16.5 million and \$21.5 million as of December 31, 2007 and 2006, respectively. In addition, as of December 31, 2007 and 2006 we owned 4,749 and 4,475 shares of Series A Convertible Preferred Stock, respectively, and warrants to purchase an additional 200,000 shares of common stock. Assuming conversion of our Series A Convertible Preferred Stock and the exercise of our warrants, we would own approximately 23% of BioSphere's common stock as of December 31, 2007. We have recorded \$507,000, \$422,000, and \$665,000 as our share of BioSphere losses for the periods ended December 31, 2007, 2006 and 2005, respectively.

### **Contractual Obligations**

Contractual obligations represent future cash commitments and liabilities under agreements with third parties and exclude contingent liabilities for which we cannot reasonably predict future payment, including contingencies related to potential future development, financing and/or commercial milestone

payments on collaboration agreements. The following chart summarizes our material contractual obligations as of December 31, 2007:

<u>Contractual Obligations</u>	<u>Total</u>	<u>2008</u>	<u>2009</u>	<u>2010</u>	<u>2011</u>	<u>2012</u>	<u>2013 and beyond</u>
	(In Thousands)						
Convertible subordinated debt—							
principal(1) . . . . .	\$720,820	\$ 72,800	\$ —	\$148,020	\$ —	\$ —	\$500,000
Capital lease obligations . . . . .	2,871	1,318	1,242	311	—	—	—
Operating leases(2) . . . . .	6,363	1,867	1,486	1,313	1,208	489	—
Purchase obligations(3) . . . . .	204,603	188,505	16,098	—	—	—	—
Total material contractual cash obligations(4) . . . . .	<u>\$934,657</u>	<u>\$264,490</u>	<u>\$18,826</u>	<u>\$149,644</u>	<u>\$1,208</u>	<u>\$489</u>	<u>\$500,000</u>

- (1) If the convertible subordinated debt were converted into common stock, these amounts would no longer be a contractual cash obligation.
- (2) Operating leases includes our leased facilities obligations.
- (3) Purchase obligations relate to research and development commitments for new and existing products and open purchase orders for the acquisition of goods and services in the ordinary course of business. Our obligation to pay certain of these amounts may be reduced or eliminated based on certain future events.
- (4) In addition to the material contractual cash obligations included in this chart, we have committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. For example, Nycomed and Bial may become entitled to receive subsequent payments of up to \$280.0 million and \$100.0 million, respectively, if all milestones are met. Because the achievement of these milestones is neither probably nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheet and have not been included in this chart. In addition, pursuant to our exclusive U.S. distribution agreement with Nycomed, we paid Nycomed an upfront payment of \$150.0 million in February 2008, which is also not reflected in this chart.

This table also excludes any liabilities pertaining to uncertain tax positions as we cannot make a reliable estimate of the period of cash settlement with the respective taxing authorities.

We have had no material related party activities in 2007 or 2006, other than those relating to the purchase of BioSphere Series A Convertible Preferred Stock and warrants.

#### **Off-Balance Sheet Arrangements**

We do not have any off-balance sheet arrangements, other than operating leases in the normal course of business, or variable interest entities or activities that include non-exchange traded contracts accounted for at fair value.

#### **Item 7A. Quantitative and Qualitative Disclosure about Market Risk.**

We are exposed to market risk from changes in interest rates and equity prices, which could affect our future results of operations and financial condition. We manage our exposure to these risks through our regular operating and financing activities.

*Interest Rates:* Our cash and cash equivalents consist of cash, money market funds, and short-term investments with original maturities of three months or less. As of December 31, 2007 the carrying

value of our cash and cash equivalents approximated fair value. Due to the conservative nature and relatively short duration of our investments, interest rate risk is mitigated. However, in a declining interest rate environment, as short-term investments mature, reinvestment occurs at less favorable market rates, negatively impacting future investment income.

Our short and long-term investments consist of U.S. government securities, certificates of deposits, corporate commercial paper, corporate bonds, asset-backed securities, equity securities and auction rate securities. Although, auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than ninety days but with contractual maturities that can be well in excess of ten years. At the end of each reset period, investors can sell or continue to hold the securities at par. These securities are subject to fluctuations in fair value depending on the supply and demand at each auction. Our long-term investments as of December 31, 2007 was \$174.0 million which includes \$99.9 million invested in highly-rated (AAA) student-loan-backed auction rate securities, of which some are associated with failed auctions in 2008. The funds associated with our auction rate securities that have failed auction may not be accessible until a successful auction occurs, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured. Additionally, the failure causes the interest rate on these investments to reset to a premium interest rate, resulting in favorable future investment income. If the credit rating of the issuer of any auction rate security held by us deteriorates, we may be required to adjust the carrying value of the investment through an impairment charge.

Although our investments are subject to credit risk and interest rate risk, our investment policy specifies credit quality standards for our investments and our investment portfolio is monitored for compliance with our investment policy. The primary objective of the investment policy is the preservation of capital. Due to the conservative nature and relatively short duration of our overall investments portfolio, credit and interest rate risk is mitigated. The interest rates on our convertible subordinated debt and capital lease obligations are fixed and, therefore, not subject to interest rate risk.

*Equity Prices:* Our convertible subordinated debt is sensitive to fluctuations in the price of our common stock into which the debt is convertible. Changes in equity prices would result in changes in the fair value of our convertible subordinated debt due to the difference between the current market price of the debt and the market price at the date of issuance of the debt. At December 31, 2007, a 10% decrease in the price of our common stock could have resulted in a decrease of approximately \$68.3 million on the net fair value of our convertible subordinated debt.

Additionally, we have a cost investment in the equity securities of ACADIA with a market value of \$20.9 million at December 31, 2007. A 10% decrease in the equity prices of these securities would result in a decrease of approximately \$2.1 million in our investments.

#### **Item 8. Financial Statements and Supplementary Data.**

The financial statements and schedules required by this item are filed as Appendix A hereto and are listed under Item 15 below.

#### **Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

There have been no disagreements with our Independent Registered Public Accounting Firm on accounting and financial disclosure matters.

#### **Item 9A. Controls and Procedures.**

##### **Disclosure Controls and Procedures**

Our management has carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer, Chief Financial Officer, and Executive Vice President, Finance,

Administration and Technical Operations, of the effectiveness of the design and operation of our disclosure controls and procedures as of December 31, 2007. The term “disclosure controls and procedures,” as defined in Rule 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, or Exchange Act, means controls and other procedures of a company that are designed to ensure that information required to be disclosed in the reports that the company files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal financial officers, as appropriate, to allow timely decisions regarding required disclosure. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures, including the possibility of human error and the circumvention or overriding of the controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation and the identification of the material weakness in internal control over financial reporting described below, the Chief Executive Officer, the Chief Financial Officer and the Executive Vice President, Finance, Administration and Technical Operations, have concluded that, as of December 31, 2007, our disclosure controls and procedures were not effective.

#### **Management’s Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting as defined in Rule 13a-15(f) or 15d-15(f) promulgated under the Exchange Act, is a process designed under the supervision of our Chief Executive Officer, Chief Financial Officer, and Executive Vice President, Finance, Administration and Technical Operations to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external reporting purposes in accordance with generally accepted accounting principals.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies and procedures may deteriorate.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company’s annual or interim financial statements will not be prevented or detected on a timely basis.

Our management has assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making its assessment, management has utilized the criteria set forth by the Committee of Sponsoring Organizations (COSO) of the Treadway Commission in *Internal Control—Integrated Framework*.

We did not establish and/or maintain effective controls over the process to identify transactions with the potential to establish a new Medicaid best price which affected the accuracy of the net revenue and product sales allowances and reserve accounts. Specifically, our controls over the calculation of Medicaid rebates were not designed to effectively monitor whether certain entities were appropriately exempt from the Medicaid best price calculation. This control deficiency resulted in the restatement of our consolidated financial statements for the years ended December 31, 2006 and 2005 and each quarter in 2006 and the first three quarters of 2007. Additionally, this control deficiency could result in misstatements of Medicaid rebate liability and corresponding revenues that would result in a material misstatement of the consolidated financial statements that would not be prevented or detected.

Accordingly, our management has determined that this control deficiency constitutes a material weakness.

Because of this material weakness, management concluded that we did not maintain effective internal control over financial reporting as of December 31, 2007, based on criteria in *Internal Control—Integrated Framework* issued by COSO.

The effectiveness of our internal control over financial reporting as of December 31, 2007 has been audited by PricewaterhouseCoopers LLP, an independent registered public accounting firm, as stated in their report, which appears on page F-2 of Appendix A to this annual report on Form 10-K.

#### **Changes in Internal Control**

There has been no change in our internal control over financial reporting during our quarter ended December 31, 2007 that have materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

#### **Remediation Plan**

The material weakness noted above was identified by year end 2007. During the first quarter of 2008, we have engaged in substantial efforts to address this material weakness and will continue to do so throughout 2008. All of these efforts will be commenced in the first or second quarter of 2008 and concluded thereafter in a timely fashion as early in 2008 as is reasonably possible. Our on-going improvements to the internal controls designed to address this material weakness will include the following, which will be undertaken with the assistance of qualified outside legal counsel:

I) Measures are and will continue to be taken to identify the cause of the material weakness in internal controls over financial reporting, through the following procedures:

- Manually review a substantial sample of entities treated as PHS covered entities by us in the past to assess whether these entities were correctly treated as covered entities. We believe there will be no impact on our historical revenue recognition but such determination is necessary for our on-going interactions with CMS and reporting and ultimate resolution with State Medicaid programs.
- Retain an outside consultant with relevant experience to implement an automated system to assess the entities that were not a part of the manual review and to retest and confirm the treatment of those entities that were part of the manual review.
- Contact entities whose status cannot be appropriately determined from the manual and automated review for additional data sufficient to identify those entities correctly.
- Initiate collection procedures against entities determined to have received PHS prices in error.
- Communicate, in writing, with CMS and HRSA regarding our determinations as to which entities are and are not considered PHS exempt during the manual and the automated review discussed above.
- Initiate, as necessary, a prior period adjustment to CMS based on recalculations of AMP and best price that result from the efforts described above.

II) The following remediation efforts will be implemented by management to remediate the material weakness of internal control over financial reporting:

- Once implemented, the automated system described above will be used on an on-going basis to assist in the evaluation of PHS-related pricing requests and the determination of which transactions should be excluded from best price.

- We will add headcount and increase training of the employees with responsibility for government contracts and the monitoring of entities eligible for PHS pricing. In particular, we will hire at least one dedicated individual to perform manual intervention for PHS pricing requests before the automated system can be implemented. This person will also perform manual interventions after the automated system is implemented to assess those customers that cannot be classified by the automated system and to retest a sample of entities that were classified by the automated system on a quarterly basis to ensure that the system is working as intended. We will also contact entities whose status cannot be appropriately determined from the manual and automated review for additional data sufficient to identify those entities correctly.
- We will be implementing appropriate policies and procedures which will address the process for qualifying, approving, and disputing PHS pricing requests and for verifying PHS eligibility.
- We are establishing monthly meetings between the contracting group and the accounting/finance group to ensure that appropriate and collaborative communications occur around the determination of best price and other price reporting and related contracting issues.
- We will retain a qualified specialist independent of the entity that assists us in implementing the automated system who will conduct an audit of PHS verification in 2008 following the completion of the manual and automated reviews and the introduction of the policies and procedures discussed above.

We anticipate that these remediation actions represent ongoing improvement measures and we expect that they will be fully implemented by year end 2008. Although we have devoted, and intend to continue to devote, significant resources to remediating the material weakness, the effectiveness of our remediation efforts will not be known until management next performs its test of internal controls.

**Item 9B. Other Information.**

None.

**PART III**

**Items 10-14.**

We have included information about our executive officers in Part I of this report under the caption "Executive Officers of the Registrant."

The information required by Part III, Items 10-14 of this report is incorporated by reference from our definitive proxy statement for our 2008 Annual Meeting of Stockholders. Such information will be contained in the sections of such proxy statement captioned "Stock Ownership of Certain Beneficial Owners and Management," "Proposal 1—Election of Directors," "Directors, Executive Officers and Corporate Governance," "Information about Executive Officer and Director Compensation," "Certain Relationships and Related Transactions, and Director Independence," "Other Matters—Section 16(a) Beneficial Ownership Reporting Compliance."

We have adopted a written code of business conduct and ethics that applies to all employees, including but not limited to, our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. We have posted our code of business conduct and ethics, and intend to disclose any amendments to, or waivers from, the code, on our web site, which is located at [www.sepracor.com](http://www.sepracor.com) in the corporate governance section.

## PART IV

### Item 15. Exhibits and Financial Statement Schedules.

The following documents are included in this Annual Report on Form 10-K.

1. The following financial statements (and related notes) of the Company are included as Appendix A hereto and are filed as part of this Annual Report on Form 10-K:

	<u>Page</u>
Report of Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets at December 31, 2007 and 2006 (as restated) . . .	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2007, 2006 (as restated) and 2005 (as restated) . . . . .	F-5
Consolidated Statements of Stockholders' Equity (deficit) and Comprehensive Income for the Years Ended December 31, 2007, 2006 (as restated) and 2005 (as restated) . . . . .	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2006 (as restated) and 2005 (as restated) . . . . .	F-7
Notes to the Consolidated Financial Statements (as restated) . . . . .	F-8

2. The schedule listed below is filed as part of this report:

Schedule II—Valuation and Qualifying Accounts and Reserves (as restated) . . .	S-1
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All other schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. The Exhibits listed in the Exhibit Index immediately preceding the Exhibits are filed as a part of this Annual Report on Form 10-K.

The following trademarks are mentioned in this report:

Sepracor, LUNESTA, XOPENEX, XOPENEX HFA and BROVANA are registered trademarks of Sepracor. OMNARIS is a registered trademark and ALVESCO is a trademark of Nycomed GmbH. This report also contains trademarks of other companies.



## SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SEPRACOR INC.

By: /s/ ADRIAN ADAMS

Adrian Adams  
*President and Chief Executive Officer*

Date: February 29, 2008

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

<u>Name</u>	<u>Title</u>	<u>Date</u>
<u>/s/ ADRIAN ADAMS</u> Adrian Adams	President, Chief Executive Officer and Director (Principal Executive Officer)	February 29, 2008
<u>/s/ DAVID P. SOUTHWELL</u> David P. Southwell	Executive Vice President, Corporate Planning, Development and Licensing and Chief Financial Officer (Principal Financial Officer)	February 29, 2008
<u>/s/ ROBERT F. SCUMACI</u> Robert F. Scumaci	Executive Vice President, Corporate Finance, Administration and Technical Operations and Treasurer (Principal Accounting Officer)	February 29, 2008
<u>/s/ TIMOTHY J. BARBERICH</u> Timothy J. Barberich	Executive Chairman and Director	February 29, 2008
<u>James G. Andress</u>	Director	
<u>/s/ DIGBY W. BARRIOS</u> Digby W. Barrios	Director	February 29, 2008
<u>/s/ ROBERT J. CRESCI</u> Robert J. Cresci	Director	February 29, 2008
<u>/s/ JAMES F. MRAZEK</u> James F. Mrazek	Director	February 29, 2008
<u>/s/ LISA RICCIARDI</u> Lisa Ricciardi	Director	February 29, 2008
<u>/s/ TIMOTHY J. RINK</u> Timothy J. Rink	Director	February 29, 2008
<u>/s/ ALAN A. STEIGROD</u> Alan A. Steigrod	Director	February 29, 2008

**APPENDIX A**  
**INDEX TO CONSOLIDATED FINANCIAL STATEMENTS**

Report of Independent Registered Public Accounting Firm . . . . .	F-2
Consolidated Balance Sheets as of December 31, 2007 and 2006 (as restated) . . . . .	F-4
Consolidated Statements of Operations for the Years Ended December 31, 2007, 2006 (as restated) and 2005 (as restated) . . . . .	F-5
Consolidated Statements of Stockholders' Equity (Deficit) and Comprehensive Income for the Years Ended December 31, 2007, 2006 (as restated) and 2005 (as restated) . . . . .	F-6
Consolidated Statements of Cash Flows for the Years Ended December 31, 2007, 2006 (as restated) and 2005 (as restated) . . . . .	F-7
Notes to Consolidated Financial Statements (as restated) . . . . .	F-8
Schedule II—Valuation and Qualifying Accounts and Reserves (as restated) . . . . .	S-1

## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Shareholders of Sepracor Inc.:

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in stockholders' equity (deficit) and comprehensive income, and of cash flows present fairly, in all material respects, the financial position of Sepracor Inc. and its subsidiaries at December 31, 2007 and 2006 and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2007 in conformity with accounting principles generally accepted in the United States of America. In addition, in our opinion, the financial statement schedule listed in the accompanying index, Appendix A, presents fairly, in all material respects, the information set forth therein when read in conjunction with the related consolidated financial statements. Also in our opinion, the Company did not maintain, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in *Internal Control—Integrated Framework* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) because a material weakness in internal control over financial reporting related to the accuracy of calculating Medicaid rebates and the corresponding revenues and related financial disclosures existed as of that date. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis. The material weakness referred to above is described in the accompanying Management's Report on Internal Control over Financial Reporting. We considered this material weakness in determining the nature, timing, and extent of audit tests applied in our audit of the December 31, 2007 consolidated financial statements and our opinion regarding the effectiveness of the Company's internal control over financial reporting does not affect our opinion on those consolidated financial statements. The Company's management is responsible for these financial statements and financial statement schedule, for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in management's report referred to above. Our responsibility is to express opinions on these financial statements, on the financial statement schedule, and on the Company's internal control over financial reporting based on our integrated audits. We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement and whether effective internal control over financial reporting was maintained in all material respects. Our audits of the financial statements included examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

As disclosed in Note B to the consolidated financial statements, the Company changed the manner in which it accounts for stock-based compensation in 2006 and the manner in which it accounts for uncertain income tax positions in 2007.

As disclosed in Note U to the consolidated financial statements, the Company has restated its 2006 and 2005 consolidated financial statements and the financial statement schedule.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal

control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ PricewaterhouseCoopers LLP  
Boston, Massachusetts  
February 29, 2008

**SEPRACOR INC.**  
**CONSOLIDATED BALANCE SHEETS**

	December 31,	
	2007	2006 (as restated)
	(In Thousands, Except Par Value Amounts)	
<b>ASSETS</b>		
Current assets:		
Cash and cash equivalents . . . . .	\$ 598,929	\$ 415,411
Short-term investments . . . . .	292,659	568,037
Accounts receivable, net of allowances of \$4,599 and \$4,821 at December 31, 2007 and 2006 . . . . .	159,644	175,103
Inventories . . . . .	53,125	37,087
Other current assets . . . . .	26,948	25,390
Total current assets . . . . .	1,131,305	1,221,028
Long-term investments . . . . .	174,031	182,876
Property and equipment, net . . . . .	87,308	72,811
Investment in affiliate . . . . .	4,313	5,107
Deferred financing costs and patents, net . . . . .	7,572	11,881
Other assets . . . . .	197	90
Total assets . . . . .	<u>\$ 1,404,726</u>	<u>\$ 1,493,793</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current liabilities:		
Accounts payable . . . . .	\$ 17,317	\$ 10,751
Accrued expenses . . . . .	210,109	113,099
Notes payable and current portion of capital lease obligation . . . . .	1,162	385
Current portion of convertible subordinated debt . . . . .	72,800	440,000
Product sales allowances and reserves . . . . .	245,839	167,631
Other current liabilities . . . . .	6,887	230
Total current liabilities . . . . .	554,114	732,096
Notes payable and capital lease obligation . . . . .	1,443	693
Deferred revenue . . . . .	24,736	—
Convertible subordinated debt . . . . .	648,020	720,820
Total liabilities . . . . .	<u>1,228,313</u>	<u>1,453,609</u>
Commitments and contingencies (Notes L and M)		
Stockholders' equity (deficit):		
Preferred stock, \$1.00 par value, 1,000 shares authorized, none outstanding at December 31, 2007 and 2006 . . . . .	—	—
Common stock, \$.10 par value, 240,000 shares authorized at December 31, 2007 and 2006; 111,955 and 110,040 shares issued; 107,694 and 105,779 shares outstanding, at December 31, 2007 and 2006, respectively . . . . .	11,195	11,004
Treasury stock, at cost (4,261 shares at December 31, 2007 and 2006) . . . . .	(232,028)	(232,028)
Additional paid-in capital . . . . .	1,858,775	1,788,417
Accumulated deficit . . . . .	(1,471,716)	(1,530,049)
Accumulated other comprehensive income . . . . .	10,187	2,840
Total stockholders' equity . . . . .	176,413	40,184
Total liabilities and stockholders' equity . . . . .	<u>\$ 1,404,726</u>	<u>\$ 1,493,793</u>

The accompanying notes are an integral part of the consolidated financial statements.

**SEPRACOR INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS**

	Year Ended December 31,		
	2007	2006 (as restated)	2005 (as restated)
	(In Thousands, Except Per Share Amounts)		
Revenues:			
Product sales .....	\$1,177,256	\$1,149,374	\$749,865
Royalties and license fees .....	47,974	33,759	51,243
Total revenues .....	<u>1,225,230</u>	<u>1,183,133</u>	<u>801,108</u>
Costs and expenses:			
Cost of products sold .....	115,835	103,760	66,682
Cost of royalties earned .....	1,320	976	749
Research and development .....	263,756	163,488	144,504
Selling, marketing and distribution .....	699,336	691,650	585,771
General and administrative .....	81,529	72,143	40,839
Litigation settlement, net .....	34,000	—	—
Restructuring expense .....	6,921	—	—
Total costs and expenses .....	<u>1,202,697</u>	<u>1,032,017</u>	<u>838,545</u>
Income (loss) from operations .....	22,533	151,116	(37,437)
Other income (expense):			
Interest income .....	46,599	46,589	27,462
Interest expense .....	(3,020)	(22,166)	(23,368)
Equity in investee losses .....	(507)	(422)	(665)
Gain on sale of equity investment .....	—	—	18,345
Other income (expense) .....	(1,002)	(300)	(79)
Income (loss) before income taxes .....	64,603	174,817	(15,742)
Income taxes .....	6,270	3,656	151
Net income (loss) .....	<u>\$ 58,333</u>	<u>\$ 171,161</u>	<u>\$ (15,893)</u>
Basic net income (loss) per common share .....	<u>\$ 0.55</u>	<u>\$ 1.63</u>	<u>\$ (0.15)</u>
Diluted net income (loss) per common share .....	<u>\$ 0.50</u>	<u>\$ 1.48</u>	<u>\$ (0.15)</u>
Shares used in computing basic and diluted net income (loss) per common share:			
Basic .....	106,847	104,943	104,839
Diluted .....	116,364	115,508	104,839

The accompanying notes are an integral part of the consolidated financial statements.

**SEPRACOR INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS'**  
**EQUITY (DEFICIT) AND COMPREHENSIVE INCOME**  
(In Thousands)

	Common Stock		Treasury Stock		Additional	Accumulated	Accumulated	Total
	Shares	Amount	Shares	Amount	Paid-in	Deficit	Other	Stockholders'
					Capital	(as restated)	Comprehensive	Equity
							Income (Loss)	(Deficit)
								(as restated)
<b>BALANCE AT DECEMBER 31, 2004</b>								
(As previously reported) . . . . .	105,309	\$10,531	1,933	\$(100,321)	\$1,411,440	\$(1,666,554)	\$13,789	\$(331,115)
Cumulative impact of restatement . . .						(18,763)		(18,763)
<b>BALANCE AT DECEMBER 31, 2004</b> .	105,309	\$10,531	1,933	\$(100,321)	\$1,411,440	\$(1,685,317)	\$13,789	\$(349,878)
Comprehensive income (loss):								
Net loss . . . . .						(15,893)		(15,893)
Foreign currency translation . . . . .							527	527
Unrealized loss on marketable equity securities . . . . .							(7,638)	(7,638)
Total comprehensive income (loss) . .								(23,004)
Issuance of common stock to employees under stock plans . . . .	3,045	304			43,743			44,047
Employee stock options exercised and settled with shares . . . . .			2	(79)				(79)
Stock compensation . . . . .					1,044			1,044
Settlement of call spread options for cash . . . . .					123,798			123,798
Settlement of call spread options for stock . . . . .			2,326	(131,628)	131,628			—
<b>BALANCE AT DECEMBER 31, 2005</b> .	108,354	\$10,835	4,261	\$(232,028)	\$1,711,653	\$(1,701,210)	\$ 6,678	\$(204,072)
Comprehensive income (loss):								
Net income . . . . .						171,161		171,161
Foreign currency translation . . . . .							(48)	(48)
Unrealized loss on marketable equity securities . . . . .							(3,790)	(3,790)
Total comprehensive income . . . . .								167,323
Issuance of common stock to employees under stock plans . . . .	1,686	169			31,564			31,733
Stock compensation . . . . .					45,200			45,200
<b>BALANCE AT DECEMBER 31, 2006</b> .	110,040	\$11,004	4,261	\$(232,028)	\$1,788,417	\$(1,530,049)	\$ 2,840	40,184
Comprehensive income (loss):								
Net income . . . . .						58,333		58,333
Foreign currency translation . . . . .							3,566	3,566
Unrealized gain on marketable equity securities . . . . .							3,781	3,781
Total comprehensive income . . . . .								65,680
Issuance of common stock to employees under stock plans . . . .	1,915	191			35,895			36,086
Stock compensation . . . . .					34,278			34,278
Tax benefit for stock compensation . .					185			185
<b>BALANCE AT DECEMBER 31, 2007</b> .	111,955	\$11,195	4,261	\$(232,028)	\$1,858,775	\$(1,471,716)	\$10,187	\$ 176,413

The accompanying notes are an integral part of the consolidated financial statements.

**SEPRACOR INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

	Year Ended December 31,		
	2007	2006	2005
		(as restated)	(as restated)
		(In Thousands)	
Cash flows from operating activities:			
Net income (loss) . . . . .	\$ 58,333	\$ 171,161	\$ (15,893)
Adjustments to reconcile net income to net cash used in operating activities:			
Depreciation and amortization . . . . .	18,664	20,724	17,154
Gain on sale of equity investment . . . . .	—	—	(18,345)
Stock compensation . . . . .	34,278	45,200	1,044
Equity in investee losses . . . . .	507	422	665
(Gain) loss on disposal of property and equipment . . . . .	(5)	(192)	803
Loss on write-off of patents . . . . .	—	245	2,129
Changes in operating assets and liabilities:			
Accounts receivable . . . . .	15,458	(34,638)	(71,551)
Inventories . . . . .	(14,699)	1,900	(25,695)
Other assets . . . . .	(1,496)	(3,033)	(3,626)
Accounts payable . . . . .	6,515	(850)	5,669
Accrued expenses . . . . .	96,843	(74,364)	60,729
Product sales allowances and reserves . . . . .	78,209	55,262	52,837
Deferred revenue . . . . .	24,659	(2,949)	(28,537)
Other liabilities . . . . .	6,734	—	—
Net cash provided by (used) in operating activities . . . . .	324,000	178,888	(22,617)
Cash flows from investing activities:			
Purchases of short and long term investments . . . . .	(851,127)	(1,076,991)	(1,293,075)
Sales and maturities of short and long term investments . . . . .	1,140,087	1,130,294	912,101
Additions to property and equipment . . . . .	(25,450)	(15,896)	(13,728)
Proceeds from sale of property and equipment . . . . .	273	150	—
Investment in non-affiliate . . . . .	—	(8,939)	(7,143)
Change in other assets . . . . .	—	28	937
Net cash provided by (used in) investing activities . . . . .	263,783	28,646	(400,908)
Cash flows from financing activities:			
Net proceeds from issuance of common stock . . . . .	36,086	31,733	43,968
Tax benefit for stock compensation . . . . .	185	—	—
Settlement of call spread options . . . . .	—	—	123,798
Repayments of long-term debt and capital leases . . . . .	(441,164)	(2,015)	(2,175)
Net cash provided by (used in) financing activities . . . . .	(404,893)	29,718	165,591
Effect of exchange rate changes on cash and cash equivalents . . . . .	628	15	173
Net increase (decrease) in cash and cash equivalents . . . . .	183,518	237,267	(257,761)
Cash and cash equivalents at beginning of year . . . . .	415,411	178,144	435,905
Cash and cash equivalents at end of year . . . . .	\$ 598,929	\$ 415,411	\$ 178,144
Supplemental schedule of cash flow information:			
Cash paid during the year for interest . . . . .	\$ 11,210	\$ 22,048	\$ 22,102
Cash paid during the year for income taxes . . . . .	\$ 4,066	\$ 3,656	\$ 151
Non cash activities:			
Capital lease obligations incurred . . . . .	\$ 3,260	\$ —	\$ 1,092

The accompanying notes are an integral part of the consolidated financial statements.



## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

We restated our consolidated financial statements for the years ended December 31, 2006 and 2005 to reduce the amount of product revenue earned during such periods due to matters related to government pricing discussed in Note U "Restatement of Financial Statements Based on Review of Government Pricing".

### A) Nature of the Business

Sepracor Inc. was incorporated in 1984 to research, develop and commercialize products for the synthesis and separation of pharmaceutical and biopharmaceutical compounds. We are now a research-based pharmaceutical company focused on the discovery, development and commercialization of differentiated products that address large and growing markets and unmet medical needs which can be marketed to primary care doctors through our sales force. Our corporate headquarters are located in Marlborough, Massachusetts.

Our consolidated financial statements include the accounts of Sepracor Inc. and our wholly-owned subsidiaries, including Sepracor Canada Limited and Sepracor N.V. Our consolidated financial statements include our investment in BioSphere Medical, Inc., or BioSphere, which is recorded under the equity method and our investments in Point Therapeutics, Inc., or Point Therapeutics (formerly known as Hemasure Inc. and HMSR Inc.), and ACADIA Pharmaceuticals Inc., or ACADIA, which we account for as marketable equity securities. During September 2005, we sold our ownership in Vicuron Pharmaceuticals Inc., or Vicuron (formerly known as Versicor, Inc.), which we had accounted for as marketable equity securities.

We and our subsidiaries are subject to risks common to companies in the industry including, but not limited to, the safety, efficacy and successful development and regulatory approval of product candidates, fluctuations in operating results, protection of proprietary technology, dependence on third-party collaboration partners and third-party sales efforts, limited manufacturing capacity, risk of product liability, compliance with government regulations and dependence on key personnel.

### B) Summary of Significant Accounting Policies

*Principles of Consolidation:* Our consolidated financial statements include our accounts and all of our wholly-owned subsidiaries accounts. All material intercompany transactions have been eliminated. Investments in affiliated companies, which are 20% to 50% owned, and over which we do not exercise control, are accounted for using the equity method. Investments in affiliated companies, which are less than 20% owned, and over which we do not exercise significant influence, are accounted for using the cost method.

*Use of Estimates and Assumptions in the Preparation of Financial Statements:* The preparation of financial statements in conformity with generally accepted accounting principles requires management to make estimates and assumptions that affect the following: (1) the reported amounts of assets and liabilities, (2) the disclosure of contingent assets and liabilities at the dates of the financial statements and (3) the reported amounts of revenues and expenses during the reporting periods. Actual results could differ materially from those estimates.

*Translation of Foreign Currencies:* The assets and liabilities of our international subsidiaries are translated into United States dollars using current exchange rates. Statement of operations amounts are translated at average exchange rates prevailing during the period. The resulting translation adjustment is recorded in accumulated other comprehensive income (loss). Foreign exchange transaction gains and losses are included in other income (expense).

*Cash and Cash Equivalents:* Cash equivalents are highly liquid, temporary cash investments having original maturity dates of three months or less.

*Short- and Long-Term Investments:* Short- and long-term investments include U.S. government securities, certificates of deposit, corporate commercial paper, corporate bonds, asset-backed securities, equity securities and auction rate securities. Those investments with a maturity of less than one year are classified as short-term. Short- and long-term investments are classified as either “available-for-sale” or “held-to-maturity”. At acquisition, we designate the appropriate classification of the investment purchased based upon its intended holding period. At each reporting date, the appropriateness of the classification is reassessed. Although auction rate securities are securities that are structured with short-term interest rate reset dates of generally less than ninety days, the contractual maturities can be well in excess of ten years, and are therefore classified as long-term investments. Available-for-sale investments are carried at fair market value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss). Realized gains and losses for securities classified as available-for-sale are included in earnings and are derived using the specific identification method for determining the cost of securities sold. Held-to-maturity investments are recorded at cost plus accrued amortization, which approximates fair value. We evaluate our investments for possible other-than-temporary impairment by reviewing factors such as the investment rating for the securities, the length of time and extent to which fair value has been below cost basis, the financial condition of the issuer and our ability and intent to hold the investment for a period of time which may be sufficient for anticipated recovery of market value. If it is determined that a decline in value is other-than-temporary an impairment charge is recorded to the extent that the carrying value of the security exceeds the estimated fair market value.

*Concentration of Credit Risk:* We have no significant off balance sheet concentration of credit risk. Financial instruments that potentially subject us to concentrations of credit risk primarily consist of the cash and cash equivalents, short- and long-term investments and trade accounts receivable.

We place our cash, cash equivalents and short- and long-term investments with high credit quality financial institutions. Our cash equivalents are highly liquid investments purchased with an original remaining maturity of three months or less. Our short and long-term investments consist of U.S. government securities, certificates of deposit, corporate commercial paper, corporate bonds, asset-backed securities, equity securities and auction rate securities. Our long-term investments as of December 31, 2007 were \$174.0 million, which includes \$99.9 million invested in highly-rated (AAA) student-loan-backed auction rate securities, of which some are associated with failed auctions in 2008. The funds associated with our auction rate securities that have failed auction may not be accessible until a successful auction occurs, a buyer is found outside of the auction process, the security is called, or the underlying securities have matured. If the credit rating of the issuer of any auction rate security held by us deteriorates, we may be required to adjust the carrying value of the investment through an impairment charge. Although our investments are subject to credit risk, our investment policy specifies credit quality standards for our investments and our investment portfolio is monitored for compliance with our investment policy. The primary objective of the investment policy is the preservation of capital. Due to the conservative nature and relatively short duration of our overall investments portfolio, credit risk is mitigated.

The percentage of total revenues from significant customers is as follows:

	Year Ended December 31,		
	2007	2006 (as restated)	2005 (as restated)
Customer A .....	31%	35%	28%
Customer B .....	29%	26%	18%
Customer C .....	17%	17%	24%
Customer D .....	10%	9%	7%

Certain prior year percentages have been reclassified to give effect for a merger of certain of our customers.

*Accounts Receivable and Bad Debt:* Our trade receivables in 2007 and 2006 primarily represent amounts due from wholesalers, distributors and retailers of our pharmaceutical products. We perform ongoing credit evaluations of our customers and we generally do not require collateral. Bad debt write-offs were not significant in 2007, 2006 and 2005; however, we monitor our receivables closely because a few customers make up a large portion of our overall revenues.

*Inventories:* Inventories are stated at the lower of cost (first-in, first-out) or market using a standard cost method. We expense costs relating to inventory until such time as we receive approval from the U.S. Food and Drug Administration, or FDA, for a new product, and then we begin to capitalize the costs relating to that product. We write down our inventory for expiration and probable quality assurance and quality control issues identified in the manufacturing process.

*Amortization, Depreciation and Certain Long-Lived Assets:* Long-lived assets include:

- **Property and Equipment**—Property and equipment are stated at cost. Costs of major additions and betterments are capitalized; maintenance and repairs, which do not improve or extend the life of the respective assets, are charged to operations. On disposal, the related cost and accumulated depreciation are removed from the accounts and any resulting gain or loss is included in the results of operations as other income (expense). Depreciation is computed using the straight-line method over the estimated useful lives of the assets. Computers and software, which are recorded in office equipment, have estimated useful lives of three years. All laboratory, manufacturing and office equipment have estimated useful lives of three to ten years. Buildings have an estimated useful life of 30 years. Leasehold improvements are amortized over the shorter of the estimated useful lives of the improvements or the remaining term of the lease.
- **Deferred Financing Costs**—Deferred financing costs relating to expenses incurred to complete convertible subordinated debt offerings are amortized evenly over the earlier of the term of the debt, or the date on which we can first be obligated to repurchase all or part of the debt.

Long-lived assets are reviewed for impairment by comparing the undiscounted projected cash flows of the related assets with their carrying amount. Impairment tests take place at least annually or whenever significant adverse events in the business or industry takes place, when a significant change in the manner an asset is used takes place or when a projection or forecast demonstrates continued losses associated with the asset. Any write-downs are treated as permanent reductions in the carrying amount of the assets.

*Revenue Recognition:* We recognize revenue from product sales, upon delivery, when title to product and associated risk of loss has passed to our customer and collectability is reasonably assured. All revenues from product sales are recorded net of applicable allowances for returns, rebates and other applicable discounts and allowances.

We receive royalties related to the manufacture, sale or use of products or technologies under license arrangements with third parties. For those arrangements where royalties are reasonably estimable, we recognize revenue based on estimates of royalties earned during the applicable period and adjust for differences between the estimated and actual royalties in the following quarter. Historically, these adjustments have not been material. For those arrangements where royalties are not reasonably estimable, we recognize revenue upon receipt of royalty statements from the licensee.

We record collaborative research and development revenue from research and development contracts over the term of the applicable contract, as we perform our obligation under the contract.

*Revenue Recognition, Multiple Element Arrangements:* We have entered into collaborative agreements with other pharmaceutical companies for the development and commercialization of our eszopiclone product outside of the United States, Canada and Mexico. These agreements are in the form of license agreements that call for nonrefundable upfront payments, milestone payments on achieving significant milestones, and royalty payments on sales if and when the compound receives marketing approval.

Our revenue recognition policy for all multiple revenue-generating arrangements are in accordance with the guidance provided in the SEC's Staff Accounting Bulletin, or SAB, No. 101, *Revenue Recognition in Financial Statements*, as amended by SAB No. 104, *Revenue Recognition*, and Emerging Issues Task Force, or EITF, Issue No. 00-21, *Revenue Arrangements with Multiple Deliverables*.

*Rebate and Return Reserves:* Certain product sales qualify for rebates from standard list pricing due to government sponsored programs or other contractual agreements. We also allow for return of our product for up to one year after product expiration. We record an estimate for these allowances as reductions of revenue at the time product sales are recorded. We derive reserves for product returns and rebates through an analysis of historical experience updated for changes in facts and circumstances as appropriate and by utilizing reports obtained from external, independent sources. Reserves for rebate programs are shown as product sales allowances and reserves on our balance sheet and were \$221.5 million and \$144.4 million at December 31, 2007 and 2006, respectively. Reserves for returns are recorded as product sales allowances and reserves on our balance sheet and were \$24.4 million and \$23.2 million at December 31, 2007 and 2006, respectively.

*Research and Development Expenses:* We expense internal and external research and development costs, including costs of funded research and development arrangements, in the period incurred. We also expense the cost of purchased technology in the period of purchase if we believe that the technology has not demonstrated technological feasibility and that it does not have an alternative future use.

*Advertising Costs:* Advertising costs are expensed as incurred. These costs are comprised of media, agency and production expenses and are included in selling, marketing and distribution expense on the consolidated statements of operations. Advertising expense for the years ended December 31, 2007, 2006 and 2005 was \$216.4 million, \$234.5 million and \$206.2 million, respectively.

*Income Taxes:* Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are determined measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. Of our total valuation allowance of \$662.1 million, approximately \$152.2 million relates to stock option compensation deductions. The tax benefit associated with the stock option compensation deductions will be credited to equity if realized. If in the future, we determine based on future profitability, that these deferred tax assets are more likely than not to be

realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods. Such release of the valuation allowance could occur within the next 12 months upon resolution of the aforementioned uncertainties.

**Derivatives:** We record all derivative instruments as either assets or liabilities in our consolidated balance sheet and measure those instruments at fair value and subsequent changes in fair value are reflected in current earnings or in accumulated other comprehensive income. In November 2004, we acquired warrants to purchase 200,000 shares of BioSphere common stock. Based on the application of the Black-Scholes option pricing model which incorporates current stock price, expected stock price volatility, expected interest rates and the expected holding period of the warrants, we determined the estimated fair value of the warrants to be \$372,000 and \$659,000 at December 31, 2007 and 2006, respectively.

**Comprehensive Income (Loss):** Comprehensive income (loss) consists of net income (loss) and other comprehensive income (loss), which includes foreign currency translation adjustments and unrealized gains and losses on available-for-sale investments.

**Basic and Diluted Net Loss Per Common Share:** Basic earnings (loss) per share, or EPS, excludes dilution and is computed by dividing income available to common shareholders by the weighted-average number of common shares outstanding for the period. Diluted EPS is based upon the weighted-average number of common shares outstanding during the period plus the additional weighted average potential common shares during the period. Potential common shares are not included in the per share calculations where the effect of their inclusion would be anti-dilutive. Potential common shares result from convertible subordinated debt and the assumed exercises of outstanding stock options, the proceeds of which are then assumed to have been used to repurchase outstanding stock options using the treasury stock method.

For the years ended December 31, 2007, 2006 and 2005, basic and diluted net income per common share is computed based on the weighted-average number of common shares outstanding during the period, however diluted net income for that period also includes the dilutive effect of common stock equivalents. Certain securities were not included in the computation of diluted earnings per share for the years ended December 31, 2007, 2006 and 2005 because they would have an anti-dilutive effect due to net income or losses for such periods. These securities include the following:

Options to purchase shares of common stock:

	2007	2006	2005
	(In Thousands, Except Per Share Data)		
Number of options . . . . .	6,751	3,184	1,919
Price range per share . . . . .	\$18.45 to \$87.50	\$52.08 to \$87.50	\$59.13 to \$87.50

Shares of common stock reserved for issuance upon conversion of convertible subordinated debt:

	2007	2006	2005
	(In Thousands)		
5% convertible subordinated debentures due 2007 . . . . .	—	4,763	4,763
0% Series A convertible senior subordinated notes due 2008 . .	—	—	—
0% Series B convertible senior subordinated notes due 2010 . .	—	—	—
Total . . . . .	—	4,763	4,763

The 0% convertible subordinated notes due 2024 are not convertible as of December 31, 2007. Shares of common stock will need to be reserved under the conversion formula for issuance upon conversion once the notes become currently convertible and our stock price exceeds \$67.20 per share.

**Stock-Based Compensation:** Effective January 1, 2006, we adopted the provisions of Statement of Financial Accounting Standards, or SFAS, No. 123(R), *Share-Based Payment*, (revised 2004), which establishes accounting for equity instruments exchanged for employee services. Under the provisions of SFAS 123(R), share-based compensation cost is measured at the grant date, based on the fair value of the award, and is recognized as an expense over the employee's requisite service period (generally the vesting period of the equity award). Prior to January 1, 2006, we accounted for share-based compensation to employees in accordance with Accounting Principles Board Opinion, or APB, No. 25, *Accounting for Stock Issued to Employees*, or APB 25, and related interpretations. We also followed the disclosure requirements of SFAS No. 123, *Accounting for Stock-Based Compensation*, or SFAS 123. We elected to adopt the modified prospective transition method as provided by SFAS 123(R) and, accordingly, financial statement amounts for the prior periods presented in this annual report on Form 10-K have not been restated to reflect the fair value method of expensing stock-based compensation.

As required by SFAS 123(R), management has made an estimate of expected stock option and restricted stock forfeitures, and we are recognizing compensation costs only for those equity awards expected to vest.

In accordance with SFAS 123(R), SFAS 109 and EITF Topic D-32, *Intraperiod Tax Allocation of the Tax Effect of Pretax Income from Continuing Operations*, we have elected to recognize any excess income tax benefits from stock option exercises in additional paid-in capital only if an incremental income tax benefit would be realized after considering all other tax attributes presently available to us. We measure the tax benefit associated with excess tax deductions related to stock-based compensation expense by multiplying the excess tax deductions by the statutory tax rates. We use the incremental tax benefit approach for utilization of tax attributes.

We estimate the fair value of stock options using the Black-Scholes valuation model. This valuation model takes into account the exercise price of the award, as well as a variety of assumptions. The assumptions we use to estimate the fair value of stock options include the expected term, the expected volatility of our stock over the expected term, the risk-free interest rate over the expected term, and our expected annual dividend yield. We believe that the valuation technique and the approach we utilized to develop the underlying assumptions are appropriate in calculating the fair values of the stock options granted in the years ended December 31, 2007 and 2006. Estimates of fair value are not intended to predict actual future events or the value ultimately realized by persons who receive equity awards.

Assumptions used to determine the fair value of stock options granted during the year ended December 31, 2007 and 2006, using the Black-Scholes valuation model, were:

	Year Ended December 31, 2007		Year Ended December 31, 2006	
	Employee Stock Option Plans	1998 Employee Stock Purchase Plan	Employee Stock Option Plans	1998 Employee Stock Purchase Plan
Expected term . . . . .	5.6 years	0.5 years	5.5 years	0.5 years
Expected volatility factor . . . . .	28%	27%	30%	31%
Risk-free interest rate . . . . .	4.45%	4.95%	4.70%	4.67%
Expected annual dividend yield . .	—	—	—	—

Prior to January 1, 2006, we accounted for stock-based compensation to employees in accordance with APB 25. We also had previously adopted the disclosure provisions of SFAS 123, which required disclosure of stock-based compensation and its impact on net loss and net loss per share. The following

table illustrates the effects on net loss and net loss per share for the year ended December 31, 2005 as if we had applied the fair value recognition provisions of SFAS 123 to stock-based employee awards.

	Year Ended December 31, 2005 (as restated)
	(In Thousands)
Net loss attributable to common stockholders .....	\$(15,893)
Add: stock-based employee compensation expense .....	1,044
Total stock-based employee compensation expense determined under fair value based method for all awards .....	(47,709)
Pro forma net loss .....	<u>\$(62,558)</u>
Amounts per common share:	
Basic—as restated .....	<u>\$ (0.15)</u>
Diluted—as restated .....	<u>\$ (0.15)</u>
Basic—pro forma .....	<u>\$ (0.60)</u>
Diluted—pro forma .....	<u>\$ (0.60)</u>

In determining the stock-based compensation expense to be disclosed under SFAS 123, we were required to estimate the fair value of stock awards granted to employees using a Black-Scholes valuation model. However, differences between the requirements of SFAS 123(R) and SFAS 123 resulted in a different set of assumptions for our valuation model, including the utilization of a forfeiture rate. Assumptions used to determine the fair value of stock options granted under SFAS 123 during the years ended December 31, 2005 were:

	Year Ended December 31, 2005	
	Employee Stock Option Plans	1998 Employee Stock Purchase Plan
Expected term .....	5.0 years	0.5 years
Expected volatility factor .....	62%	36%
Risk-free interest rate .....	3.98%	2.73%
Expected annual dividend yield .....	—	—

We have never declared cash dividends on any of our capital stock and do not expect to do so in the foreseeable future.

The effects on 2005 pro forma net loss and net loss per share of expensing the estimated fair value of stock options and common shares issued pursuant to the stock option and stock purchase plans are not necessarily representative of the effects on reported results of operations for future years as options vest over several years and we intend to grant varying levels of stock options in future periods.

#### Recent Accounting Pronouncements:

In December 2007, the Financial Accounting Standards Board, or FASB, issued SFAS No.160, *Noncontrolling Interests in Consolidated Financial Statements—an amendment of ARB No. 51*, or SFAS 160. SFAS 160 establishes accounting and reporting standards for the noncontrolling interest in a subsidiary and for the deconsolidation of a subsidiary. It clarifies that a noncontrolling interest in a subsidiary is an ownership interest in the consolidated entity that should be reported as equity in the consolidated financial statements. This pronouncement will be effective for fiscal years beginning on or after December 15, 2008. SFAS 160 requires retroactive adoption of the presentation and disclosure requirements for existing minority interests. All other requirements of SFAS 160 shall be applied prospectively. We do not expect the adoption of SFAS 160 to have a material impact on our consolidated financial statements.

In December 2007, the Emerging Issues Task Force of the FASB, or EITF, reached a consensus on Issue No. 07-1, *Accounting for Collaborative Arrangements*, or EITF 07-1. The EITF concluded on the definition of a collaborative arrangement and that revenues and costs incurred with third parties in connection with collaborative arrangements would be presented gross or net based on the criteria in EITF No. 99-19, *Reporting Revenue Gross as a Principal versus Net as an Agent*, or EITF 99-19, and other accounting literature. Based on the nature of the arrangement, payments to or from collaborators would be evaluated and the terms of the arrangement the nature of the entity's business and whether those payments are within the scope of other accounting literature would be presented. Companies are also required to disclose the nature and purpose of collaborative arrangements along with the accounting policies and the classification and amounts of significant financial-statement amounts related to the arrangements. Activities in the arrangement conducted in a separate legal entity should be accounted for under other accounting literature; however, required disclosure under EITF 07-1 applies to the entire collaborative agreement. EITF 07-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years, and is to be applied retrospectively to all periods presented for all collaborative arrangements existing as of the effective date. We do not expect the adoption of EITF 07-01 to have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141(R), *Business Combinations*, which will require an acquiring company to measure all assets acquired and liabilities assumed, including contingent considerations and all contractual contingencies, at fair value as of the acquisition date. In addition, an acquiring company is required to capitalize in-process research and development and either amortize it over the life of the product, or write it off if the project is abandoned or impaired. SFAS No. 141(R) is effective for transactions occurring on or after January 1, 2009. We are evaluating the impact this standard will have on our financial statements.

In February 2007, the FASB issued Statement of Financial Accounting Standards, or SFAS, No. 159, *The Fair Value Option for Financial Assets and Financial Liabilities*, or SFAS 159, which allows entities the option to measure eligible financial instruments and certain other items at fair value. SFAS 159 is effective for fiscal years beginning after November 15, 2007. We do not expect the adoption of SFAS 159 to have a material impact on our consolidated financial statements.

In September 2006, the FASB issued SFAS No. 157, *Fair Value Measurements*, or SFAS 157. This pronouncement defines fair value, establishes a framework for measuring fair value and expands disclosures about fair value measurements. SFAS 157 is effective for fiscal years beginning after November 15, 2007. On November 14, 2007, the FASB agreed to a one-year deferral for the implementation of SFAS 157 for other non-financial assets and liabilities. We do not expect the adoption of SFAS 157 to have a material impact on any non-financial assets and liabilities or on our consolidated financial statements.

### **C) Investment in Affiliate**

BioSphere was a consolidated subsidiary from 1994 through July 2, 2001. As a result of a public offering of BioSphere common stock in 2001, our ownership of BioSphere was reduced from approximately 55% to 26%. Therefore, effective July 3, 2001, we changed the method of accounting for our investment in BioSphere from consolidating the results of BioSphere operations to the equity method. On November 10, 2004, we purchased from BioSphere, in a private placement, 4,000 shares of BioSphere Series A Convertible Preferred Stock and warrants to purchase an additional 200,000 shares of BioSphere common stock for an aggregate purchase price of \$4.0 million. Each share of BioSphere Series A Convertible Preferred Stock is convertible into 250 shares of BioSphere common stock at a conversion price of \$4.00 per share. In addition, quarterly dividends of 6% per annum are paid on the shares either in cash or additional shares of Series A Convertible Preferred Stock at BioSphere's election and, as of December 31, 2007, we had acquired an additional 749 shares of Series A Convertible Preferred Stock in connection with dividend payments.



At December 31, 2007 and 2006, we owned 3,224,333 shares, or approximately 18% of BioSphere's outstanding common stock. The cost basis of those shares is \$4.4 million, and the fair market value of those shares was approximately \$16.5 million and \$21.5 million as of December 31, 2007 and 2006, respectively. In addition, as of December 31, 2007 and 2006, we owned 4,749 and 4,475 shares of Series A Convertible Preferred Stock, respectively, and warrants to purchase an additional 200,000 shares of common stock, which based on the application of the Black-Scholes option pricing model, we determined the estimated fair value of the warrants to be \$372,000 and \$659,000 at December 31, 2007 and 2006, respectively, which was recorded as an investment in affiliate. Assuming conversion of our Series A Convertible Preferred Stock and the exercise of our warrants, we would own approximately 23% and 24% of BioSphere's common stock as of December 31, 2007 and 2006, respectively. We recorded \$507,000, \$422,000 and \$665,000 as our share of BioSphere's losses for the years ended December 31, 2007, 2006 and 2005, respectively.

**D) Cash, Cash Equivalents and Short-Term and Long-Term Investments**

Cash and cash equivalents consist of the following at December 31:

	2007	2006
	(In Thousands)	
Cash and cash equivalents:		
Cash and money market funds . . . . .	\$598,929	\$364,115
Corporate and government commercial paper . . . . .	—	51,296
Total cash and cash equivalents . . . . .	<u>\$598,929</u>	<u>\$415,411</u>

Due to the nature of our investments, amortized cost approximates market value as of December 31, 2007 and 2006.

Short and long-term investments classified as available-for-sale or held-to-maturity consist of the following at December 31:

	2007		2006	
	Available- For-Sale	Held-to- Maturity	Available- For-Sale	Held-to- Maturity
	(In Thousands)			
Due within 1 year:				
Corporate and bank obligations . . . . .	\$ 18,958	\$212,024	\$27,524	\$173,974
Government and agency securities . . . . .	1,988	59,689	1,170	365,369
Equity securities . . . . .	—	—	—	—
Due in greater than 1 year:				
Corporate and bank obligations(1) . . . . .	115,321	37,783	34,713	131,100
Government and agency securities . . . . .	—	—	—	—
Equity securities . . . . .	20,927	—	17,063	—
Total short-term and long-term investments . . . . .	<u>\$157,194</u>	<u>\$309,496</u>	<u>\$80,470</u>	<u>\$670,443</u>

- (1) December 31, 2007 and 2006 includes \$99.9 million and \$131.1 million, respectively, invested in highly-rated (AAA) student-loan-backed auction rate securities. At December 31, 2006, these securities were classified as held-to-maturity. At December 31, 2007, based on our review of our investment classification, we re-classified all our auction rate securities to available-for-sale, which resulted in no adjustment to our consolidated financial statements as these securities had no unrealized gain or loss at the time of the reclassification. In 2008, some of our auction rate securities are associated with failed auctions. The funds associated with our auction rate securities that failed auction, may not be accessible until a successful auction occurs, a buyer is found outside

of the auction process, the security is called, or the underlying securities have matured. If the credit rating of the issuer of any auction rate security held by us deteriorates, we may be required to adjust the carrying value of the investment through an impairment charge, however we have not recorded an impairment charge related to our auction rate securities given our ability and intent to hold these securities until liquidity is restored. In addition, based on the student-loan-backed guarantee associated with these securities, we do not believe there has been a material decline in the market value of our auction rate securities.

Held-to-maturity securities are recorded at cost plus accrued amortization, which approximates fair value. Realized gains and losses on held-to-maturity securities were insignificant in 2007 and 2006.

Available-for-sale securities are carried at fair market value with unrealized gains and losses recorded as a component of accumulated other comprehensive income (loss). Investments with continuous unrealized losses greater than one year were immaterial in 2007 and 2006. Management does not believe any unrealized losses represent an other-than-temporary impairment based on our evaluation of available evidence as of December 31, 2007. The following is a summary of available-for-sale securities:

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(In Thousands)				
<b>December 31, 2007</b>				
Corporate and bank obligations(1) . . . . .	\$139,353	\$ 63	\$137	\$139,279
Government and agency securities . . . . .	1,988	1	1	1,988
Equity securities . . . . .	16,082	4,847	2	20,927
	<u>\$157,423</u>	<u>\$4,911</u>	<u>\$140</u>	<u>\$162,194</u>

- (1) At December 31, 2006, our auction rate securities were classified as held-to-maturity. At December 31, 2007, based on our review of our investment classification, we re-classified the auction rate securities to available-for-sale.

Type of Security	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
(In Thousands)				
<b>December 31, 2006</b>				
Corporate and bank obligations . . . . .	\$62,219	\$ 42	24	\$62,237
Government and agency securities . . . . .	1,179	—	9	1,170
Equity securities . . . . .	16,082	2,773	1,792	17,063
	<u>\$79,480</u>	<u>\$2,815</u>	<u>\$1,825</u>	<u>\$80,470</u>

Realized gains on available-for-sale securities were \$0 in 2007 and 2006 and \$18.3 million in 2005.

Our available-for-sale securities include our equity investments in ACADIA at December 31, 2007 and Point Therapeutics and ACADIA at December 31, 2006.

We accounted for our investment in Point Therapeutics using the cost method because we do not have significant influence over the operations of Point Therapeutics. As of December 31, 2007, we owned 433,333 shares of Point Therapeutics, which had a cost basis and a market value of approximately \$0. At December 31, 2006, this investment had market value of approximately \$446,000 and a cost basis of \$0.

On June 15, 2005, Vicuron entered into an agreement and plan of merger with Pfizer, Inc., where Pfizer agreed to purchase all outstanding shares of Vicuron for a purchase price of \$29.10 per share in cash. The merger closed on September 11, 2005 and we received cash proceeds of approximately \$20.0 million in exchange for our remaining 687,766 shares of Vicuron common stock. In accordance with the cost method and the classification of our investment in Vicuron as available-for-sale, we were carrying our investment at fair market value with the corresponding unrealized gain recorded through equity. Upon closing of the merger, we recognized the unrealized gain of approximately \$18.3 million and included that amount in other income on the consolidated statements of operations. At December 31, 2007, 2006 and 2005, we had no ownership in Vicuron.

In January 2005, we entered into a collaboration agreement with ACADIA Pharmaceuticals, Inc., or ACADIA, for the development of new drug candidates targeted toward the treatment of CNS disorders. This agreement expired pursuant to its terms in January 2008 and we are no longer pursuing the development of the drug candidates subject to this agreement.

In 2005, under the terms of the collaboration agreement with ACADIA, we completed the initial \$10.0 million purchase of ACADIA common stock in connection with the collaboration. Our purchase was made at a price of approximately \$9.28 per share, which represented a 40 percent premium over the 30-day trailing average closing price of ACADIA's common stock on the NASDAQ Global Market and resulted in the issuance to us of 1,077,029 shares of ACADIA common stock. We recorded the premium amount of \$2.9 million as research and development expense and the remaining amount of \$7.1 million as an investment in ACADIA.

In 2006, under the terms of the collaboration agreement with ACADIA, we completed the second \$10.0 million purchase of ACADIA common stock in connection with the collaboration between the two companies that was formed in January 2005. Our purchase was made at a price of approximately \$12.29 per share, which represented a 25 percent premium over the 30-day trailing average closing price of ACADIA's common stock on the NASDAQ Global Market and resulted in the issuance to us of 813,393 shares of ACADIA common stock. We recorded the premium amount of \$1.1 million as research and development expense and the remaining amount of \$8.9 million as an investment in ACADIA.

At December 31, 2007 and 2006, we owned 1,890,422 shares of ACADIA's common stock. The fair market value of those shares was approximately \$20.9 million and \$16.6 million as of December 31, 2007 and 2006, respectively.

#### **E) Accounts Receivable**

Our trade receivables in 2007 and 2006 primarily represent amounts due from wholesalers, distributors and retailers of our pharmaceutical products. We perform ongoing credit evaluations of our customers and generally do not require collateral. Our allowance for doubtful accounts was \$459,000 and \$470,000 at December 31, 2007 and 2006, respectively, and our allowance for payment term discounts related to accounts receivable was \$4.1 million and \$4.4 million at December 31, 2007 and 2006, respectively.

Customers with amounts due that represent greater than 10% of our accounts receivable balance are as follows at December 31:

	<u>2007</u>	<u>2006</u>
Customer A .....	29%	31%
Customer B .....	33%	24%
Customer C .....	12%	25%
Customer D .....	15%	10%

Certain prior year percentages have been adjusted to give retroactive effect for a merger of certain of our customers.

**F) Inventories**

Inventories consist of the following at December 31:

	<u>2007</u>	<u>2006</u>
	<u>(In Thousands)</u>	
Raw materials .....	\$26,811	\$21,611
Finished goods .....	26,314	15,476
	<u>\$53,125</u>	<u>\$37,087</u>

**G) Property and Equipment**

Property and equipment consist of the following at December 31:

	<u>2007</u>	<u>2006</u>
	<u>(In Thousands)</u>	
Land .....	\$ 4,181	\$ 4,125
Building .....	50,927	47,999
Laboratory and manufacturing equipment .....	50,233	38,041
Office equipment .....	61,683	53,477
Leasehold improvements .....	3,064	2,919
	<u>170,088</u>	<u>146,561</u>
Accumulated depreciation and amortization .....	<u>(82,780)</u>	<u>(73,750)</u>
	<u>\$ 87,308</u>	<u>\$ 72,811</u>

Property and equipment under capital leases at December 31, 2007 and 2006 was \$3.7 million and \$5.8 million, respectively. Accumulated amortization related to property and equipment under capital leases at December 31, 2007 and 2006 was \$1.2 million and \$5.3 million, respectively. Depreciation expense was \$15.4 million, \$15.6 million and \$12.7 million including amortization on capital leases of \$1.0 million, \$1.6 million and \$2.0 million for the years ended December 31, 2007, 2006 and 2005, respectively.

**H) Deferred Financing Costs and Patents**

Deferred financing costs and patents, net, consist of the following at December 31:

	<u>2007</u>	<u>2006</u>
	<u>(In Thousands)</u>	
Deferred finance costs, gross .....	\$ 20,407	\$ 34,440
Accumulated amortization .....	<u>(13,336)</u>	<u>(23,215)</u>
Deferred finance costs, net .....	<u>\$ 7,071</u>	<u>\$ 11,225</u>
Patents, gross .....	\$ 2,259	\$ 2,259
Accumulated amortization .....	<u>(1,758)</u>	<u>(1,603)</u>
Patents, net .....	<u>\$ 501</u>	<u>\$ 656</u>

Amortization of intangible assets is computed on the straight-line method based on the estimated useful lives of the assets. The following schedule details our amortization expense related to patents and deferred financing costs:

	Year Ended December 31,		
	2007	2006	2005
	(In Thousands)		
Amortization of deferred finance costs . . . . .	\$4,154	\$5,741	\$6,274
Amortization of patents . . . . .	155	231	535
Total amortization . . . . .	<u>\$4,309</u>	<u>\$5,972</u>	<u>\$6,809</u>

During 2006, we wrote off unamortized patents and other intangible assets of \$245,000 related to various compounds we are no longer pursuing. The estimated aggregate amortization expense for each of the next five years is as follows: 2008, \$3.9 million; 2009, \$2.8 million; 2010, \$685,000; 2011, \$109,000; and 2012, \$16,300.

We have no goodwill recorded at December 31, 2007 or 2006.

#### I) Accrued Expenses

Accrued expenses consist of the following at December 31:

	2007	2006
	(In Thousands)	
Research and development costs . . . . .	\$ 19,437	\$ 12,993
Sales and marketing costs . . . . .	30,969	20,561
Interest on convertible subordinated debt . . . . .	—	8,250
Compensation costs . . . . .	37,084	33,783
Licensing fee . . . . .	67,500	—
Other . . . . .	55,119	37,512
Total accrued expenses . . . . .	<u>\$210,109</u>	<u>\$113,099</u>

#### J) Notes Payable and Capital Lease Obligations

Notes payable and capital lease obligations consist of the following at December 31:

	2007	2006
	(In Thousands)	
Government grant from Nova Scotia Department of Economic Development(1) . . . . .	\$ —	\$ 570
Obligations under capital leases (See Note L) . . . . .	2,605	508
Total . . . . .	<u>2,605</u>	<u>1,078</u>
Less current portion . . . . .	<u>(1,162)</u>	<u>(385)</u>
Total long-term portion . . . . .	<u>\$ 1,443</u>	<u>\$ 693</u>

- (1) Our wholly-owned subsidiary, Sepracor Canada Limited, has met certain conditions under a Canadian Government grant, which relieved Sepracor Canada Limited of its obligation under that grant.

# **K) Convertible Subordinated Debt**

Convertible subordinated debt, including current portion, consists of the following at December 31:

	2007		2006	
	Carrying Amount	Fair Value(1)	Carrying Amount	Fair Value(1)
(In Thousands)				
5% convertible subordinated debentures due 2007 . . . .	\$ —	\$ —	\$ 440,000	\$ 439,472
0% Series A convertible senior subordinated notes due 2008 . . . . .	72,800	74,518	72,800	140,591
0% Series B convertible senior subordinated notes due 2010 . . . . .	148,020	156,783	148,020	286,211
0% convertible senior subordinated notes due 2024 . . .	500,000	451,900	500,000	539,400
Total . . . . .	<u>\$720,820</u>	<u>\$683,201</u>	<u>\$1,160,820</u>	<u>\$1,405,674</u>

(1) The fair value of all the convertible subordinated debt is from a quoted market source.

In February 2007, we paid in full \$440.0 million in principal amount of outstanding 5% convertible debentures, which matured on February 15, 2007, plus approximately \$11.0 million in accrued interest. The \$440.0 million of 5% debentures were convertible into common stock, at the option of the holder, at a price of \$92.38 per share, and the 5% interest was paid semi-annually, commencing on August 15, 2000. The 5% debentures were redeemable at our option if the trading price of our common stock exceeded \$110.86, which is equal to 120% of the conversion price, for 20 trading days in a period of 30 consecutive trading days. As part of the sale of the 5% debentures, we incurred \$14.0 million of offering costs, which were recorded as other assets and were amortized over seven years, the term of the 5% debentures. In December 2003, we issued an aggregate of \$600.0 million of 0% convertible senior subordinated notes, or 0% notes. We issued \$200.0 million in principal amount of 0% Series A convertible senior subordinated notes due 2008, or 0% Series A notes due 2008, and \$400.0 million in principal amount of 0% Series B convertible senior subordinated notes due 2010, or 0% Series B notes due 2010. In January 2004, pursuant to an option granted to the initial purchasers of our 0% notes, we issued an additional \$50.0 million of 0% Series A notes due 2008 and \$100.0 million of 0% Series B notes due 2010. The 0% notes are convertible into common stock, at the option of the holder, at a price of \$31.89 and \$29.84 per share for the 0% Series A notes due 2008 and 0% Series B notes due 2010, respectively. The 0% notes do not bear interest and are not redeemable. We may be required to repurchase the 0% notes at the option of the holders if there is a change in control of Sepracor or the termination of trading of our common stock on NASDAQ or similar markets. As part of the sale of the 0% notes, we incurred offering costs of \$16.9 million, which have been recorded as deferred financing costs and are being amortized over the term of the notes on a pro-rata basis based on the total amount of 0% notes issued. Net of issuance costs, our proceeds were approximately \$145.9 million. The issuance costs have been recorded as deferred financing costs and are being amortized over 4 and 6 years, respectively, the remaining term of the debt. During September 2004, certain holders of our 0% Series A notes due 2008 and 0% Series B notes due 2010, agreed, in separately negotiated transactions, to convert \$177.2 million and \$352.0 million in aggregate principal amount of their 0% Series A notes due 2008 and 0% Series B notes due 2010, respectively, into an aggregate of 5,556,104 and 11,797,483 shares of our common stock, respectively. As an inducement to convert their notes, we paid the holders of the 0% Series A notes due 2008 and 0% Series B notes due 2010 aggregate cash payments of \$23.9 million and \$45.9 million, respectively. These amounts were recorded as a loss on conversion of convertible notes. Deferred financing costs related to the converted 0% Series A notes due 2008 and 0% Series B notes due 2010 of \$4.2 million and \$8.8 million, respectively, were netted against the amount of debt converted into equity. At December 31, 2007 and 2006, \$72.8 million and

\$148.0 million of the 0% Series A notes due 2008 and 0% Series B notes due 2010, respectively, remained outstanding.

In September 2004, we issued \$500.0 million in principal amount of 0% convertible senior subordinated notes due 2024, or 0% notes due 2024. Holders may convert the notes into cash and, if applicable, shares of our common stock at a conversion rate of 14.8816 shares of common stock per \$1,000 principal amount of notes (which is equal to a conversion price of approximately \$67.20 per share), subject to adjustment, before the close of business on the business day immediately preceding October 15, 2024 only under the following circumstances:

- during any fiscal quarter beginning after December 31, 2004, if the closing sale price of our common stock for at least 20 trading days in the 30 consecutive trading days ending on the last day of the preceding fiscal quarter is more than 130% of the conversion price per share of common stock on the last day of such preceding quarter;
- during the five business day period following any five consecutive trading day period (the "measurement period") in which the trading price per note on each day of that measurement period is less than 98% of the closing sale price of our common stock multiplied by the conversion rate on each such day;
- if the notes have been called for redemption;
- upon the occurrence and continuance of specified corporate transactions; and
- in connection with a transaction or event constituting a fundamental change occurring on or prior to October 20, 2009.

Upon conversion of the notes, if the adjusted conversion value of the notes, which is defined as the product of (1) the conversion rate in effect on the conversion date; and (2) the average of the daily volume weighted average price of our common stock for each of the five consecutive trading days beginning on the second trading day immediately following the day the notes are tendered for conversion, is less than or equal to the principal amount of the notes, then we will convert the notes for an amount in cash equal to the adjusted conversion value of the notes. If the adjusted conversion value of the notes is greater than the principal amount of the notes, then we will convert the notes into whole shares of our common stock for an amount equal to the adjusted conversion value of the notes less the principal amount of the notes, plus an amount in cash equal to the principal amount of the notes plus the cash value of any fractional shares of our common stock. During 2007, none of the listed circumstances occurred and there was no conversion of debt.

The notes do not bear interest. On or after October 20, 2009, we have the option to redeem for cash all or part of the notes at any time at a redemption price equal to 100% of the principal amount of the notes to be redeemed. We may be required by the note holders to repurchase for cash all or part of the notes on October 15 of 2009, 2014 and 2019 at a repurchase price equal to 100% of the principal amount of the notes to be repurchased. We may be required to repurchase for cash all or part of the notes upon a change in control of Sepracor or a termination of trading of our common stock on the NASDAQ or similar markets at a repurchase price equal to 100% of the principal amount of the notes to be repurchased, plus in certain change in control circumstances, an additional make-whole payment. In connection with the sale of the notes, we incurred offering costs of approximately \$14.2 million, which have been recorded as deferred financing costs and are being amortized over 5 years, the note holders first potential redemption date. At December 31, 2007 and 2006, \$500.0 million of the 0% notes due 2024 remained outstanding.

## L) Commitments and Contingencies

### Lease Payments

Future minimum lease payments under all non-cancelable leases in effect at December 31, 2007, are as follows:

<u>Year</u>	<u>Operating Leases</u>	<u>Capital Leases</u>
	<u>(In Thousands)</u>	
2008 .....	1, 867	1,318
2009 .....	1,486	1,242
2010 .....	1,313	311
2011 .....	1,208	—
2012 .....	489	—
Thereafter .....	—	—
Total minimum lease payments .....	<u>\$6,363</u>	<u>2,871</u>
Less amount representing interest .....		<u>(266)</u>
Present value of minimum lease payments .....		<u>\$2,605</u>

Future minimum lease payments under operating leases relate primarily to our office, laboratory and production facilities at 33 Locke Drive, and our office facilities at 111 Locke Drive, both in Marlborough, Massachusetts. Most of the lease terms provide options to extend the leases and require us to pay our allocated share of taxes and operating costs in addition to the annual base rent payments.

Our capital leases relate to laboratory and computer equipment purchased under capital lease agreements.

Rental expense under operating leases amounted to \$1.5 million, \$1.3 million and \$833,000 for the years ended December 31, 2007, 2006 and 2005, respectively.

### Collaboration Agreements

We have committed to make potential future milestone payments to third parties as part of licensing, distribution and development agreements. Payments under these agreements generally become due and payable only upon achievement of certain development, regulatory and/or commercial milestones. We may also be required to make additional payments to Nycomed and Bial of up to \$280.0 million and \$100.0 million, respectively, if all milestones under the agreements with these parties are met. Because the achievement of these milestones is neither probably nor reasonably estimable, such contingent payments have not been recorded on our consolidated balance sheet.

### Indemnification Obligations

We enter into standard indemnification agreements in our ordinary course of business, under which we indemnify and hold harmless certain parties, including customers such as wholesalers, against claims, liabilities and losses brought by third parties to the extent that the claims arise out of (1) injury or death to person or property caused by defect in our product, (2) negligence in the manufacture or distribution of the product or (3) a material breach by Sepracor. We have no liabilities recorded for these guarantees at December 31, 2007 and, if liabilities were incurred, we have insurance policies covering product liabilities, which would mitigate any losses.

Under our certificate of incorporation we indemnify our officers and directors for certain events or occurrences while the officer or director is, or was, serving at our request in such capacity. The term of the indemnification period is for the officer's or director's lifetime. The maximum potential amount of



future payments we could be required to make under the terms of our certificate of incorporation is unlimited, however, we believe the fair value of this indemnification is minimal.

## **M) Litigation**

### ***Litigation Related to Generic Competition and Patent Infringement***

Patent litigation involves complex legal and factual questions. We can provide no assurance concerning the outcome or the duration of any patent related lawsuits. If we, or third parties from whom we receive royalties, are not successful in enforcing our respective patents, the companies seeking to market generic versions of our drugs and the drugs of our licensees will not be excluded, for the full term of the respective patents, from marketing their generic versions of our products or third party products for which we have licensed rights to our patents. Introduction of generic copies of any of our products or third party products for which we have licensed rights to our patents before the expiration of our patents would have a material adverse effect on our business, financial condition and results of operations.

#### **Levalbuterol Hydrochloride Inhalation Solution Abbreviated New Drug Applications**

In September 2005, we received notification that the FDA had received an ANDA from Breath seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Breath's submission includes a Paragraph IV certification alleging that our patents listed in the FDA publication entitled *Approved Drug Products With Therapeutic Equivalence Evaluations*, commonly referred to as the "Orange Book," for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Breath is seeking approval. In October 2005, we filed a civil action against Breath for patent infringement and a non-jury trial is scheduled to begin on July 14, 2008 in the United States District Court for the District of Massachusetts, No. CV:06-10043.

In January 2006, we received notification that the FDA had received an ANDA from Dey, L.P., seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL, and 0.31 mg/3 mL XOPENEX Inhalation Solution. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. is seeking approval. In February 2006, we filed a civil action against Dey, L.P. for patent infringement and the case is pending in the United States District Court for the District of Delaware, C.A. No. 06-113.

In August 2006, we received notification that the FDA had received an ANDA from Dey, L.P. seeking approval of a generic version of our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate. Dey, L.P.'s submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate are invalid, unenforceable, or not infringed by the generic version for which Dey, L.P. is seeking approval. In September 2006, we filed a civil action against Dey, L.P. for patent infringement in the United States District Court for the District of Delaware, C.A. No. 06-604. In September 2006, both civil actions we filed against Dey, L.P. were consolidated into a single suit. No trial date has been set.

In May 2007, we received notification that the FDA had received an ANDA from Barr seeking approval of a generic version of our 1.25 mg/3 mL, 0.63 mg/3 mL and 0.31 mg/3 mL XOPENEX Inhalation Solution. Barr's submission includes a Paragraph IV certification alleging that our patents listed in the Orange Book for these three dosages of XOPENEX Inhalation Solution are invalid, unenforceable or not infringed by the generic version for which Barr is seeking approval. In July 2007, we filed a civil action against Barr for patent infringement and the case is pending in the United States District Court for the District of Delaware, C.A. No. 07-438. No trial date has been set.

The filing of an action for patent infringement under the Hatch-Waxman Act invokes an automatic 30-month stay of the FDA's authority to grant final marketing approval to those companies that file an ANDA containing a Paragraph IV certification against one or more of our XOPENEX Inhalation Solution patents. The first filer of an ANDA with a Paragraph IV certification is potentially entitled to a 180-day period of semi-exclusivity during which the FDA cannot approve subsequently filed ANDAs. The 180-day semi-exclusivity period would begin to run only upon first commercial marketing by the first filer. There are, however, also certain events that could cause the first filer to forfeit the 180-day semi-exclusivity period, which we refer to as a forfeiture event.

For our 1.25 mg/3 mL, 0.6 $\frac{2}{3}$  mL, and 0.3 $\frac{1}{2}$  mL XOPENEX Inhalation Solution, we believe that Breath is the first filer and potentially entitled to 180-days of semi-exclusivity against subsequent ANDA filers for those three dosages. The 30-month stay against Breath's ANDA is scheduled to expire on or about March 7, 2008. In December 2007, the FDA granted tentative approval to Breath's ANDA for all three dosages. Upon expiration of that 30-month stay, the FDA could grant final approval and Breath could then commence an "at risk" distribution of its generic levalbuterol product for those dosages notwithstanding our patents and notwithstanding that the court's decision as to the merits of the litigation will not have been rendered, unless we were able to obtain an injunction prohibiting such distribution. However, if a forfeiture event occurs and the FDA determines that Breath has forfeited the 180-day semi-exclusivity period for those three dosages, other ANDA filers who have been granted final approval by the FDA could commence an "at risk" launch upon expiration of the 30-month stay. For those three dosages, the 30-month stays against Dey, L.P. and Barr expire on or about July 9, 2008 and November 30, 2009, respectively.

For our 1.25 mg/0.5 mL XOPENEX Inhalation Solution concentrate, we believe that Dey, L.P. is the first filer and potentially entitled to 180-days of semi-exclusivity for that concentration. The 30 month stay against Dey, L.P.'s ANDA for that concentration expires on or about February 14, 2009.

Although we could seek recovery of any damages sustained in connection with any activities conducted by a party that infringe a valid and enforceable claim in our patents, whether we are ultimately entitled to such damages would be determined by the court in connection with our ongoing legal proceedings with each party desiring to launch generic levalbuterol hydrochloride products. If any of these parties were to commence selling a generic alternative to our XOPENEX Inhalation Solution product prior to the resolution of these ongoing legal proceedings, or there is a court determination that the products these companies wish to market do not infringe our patents, or that our patents are invalid or unenforceable, it would have a material adverse effect on our business, financial condition and results of operations. In addition, our previously issued guidance regarding our projected financial results may no longer be accurate and we would have to revise such guidance.

#### **Desloratadine Abbreviated New Drug Applications**

In June 2007, we received notification that the FDA had received an ANDA from Glenmark Pharmaceuticals, Ltd. and Glenmark Pharmaceuticals, Inc., USA, which we refer to collectively as Glenmark, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Glenmark's submission includes a Paragraph IV certification alleging that our patents that Schering-Plough (as licensee of such patents) listed in the Orange Book for its CLARINEX are invalid, unenforceable or not infringed by the generic version for which Glenmark is seeking approval. In July 2007, we and the University of Massachusetts, co-owners of certain patents listed in the Orange Book, filed a civil action in the United States District Court for the District of New Jersey against Glenmark for patent infringement, C.A. No. 07-3385.

In July 2007, we received notification that the FDA had received an ANDA from Sun Pharmaceutical Industries, Ltd., or Sun, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Sun's submission includes a Paragraph IV certification alleging that our

patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable, or are not infringed by the generic version for which Sun is seeking approval. In September 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Sun for patent infringement, C.A. No. 07-4213.

In August 2007, we received notification that the FDA had received an ANDA from Orchid Chemicals & Pharmaceuticals, Ltd., or Orchid, seeking approval of a generic version of Schering-Plough's 5 mg tablets, and 2.5 and 5 mg orally disintegrating tablets of CLARINEX. Orchid's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic version for which Orchid is seeking approval. In October 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Orchid for patent infringement, C.A. No. 07-4623.

In September 2007, we received notification that the FDA had received ANDAs from Mylan Pharmaceuticals, Inc., or Mylan, Lupin Limited, or Lupin, and Perrigo R & D Company, or Perrigo, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX, and from Dr. Reddy's Laboratories, or Dr. Reddy's, seeking approval of generic versions of Schering-Plough's (1) 5 mg tablets of CLARINEX, (2) 2.5 mg and 5 mg orally disintegrating tablets of CLARINEX, (3) 2.5/120 mg tablets of CLARINEX-D 12 hour desloratadine and pseudoephedrine and (4) 5.0/240 mg tablets of CLARINEX-D 24 hour desloratodine and pseudoephedrine extended release tablets. The submissions by these parties include Paragraph IV certifications alleging that certain patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic versions for which these parties are seeking approval. In October 2007, we and the University of Massachusetts filed civil actions in the United States District Court for the District of New Jersey against Mylan, Lupin, Perrigo and Dr. Reddy's for patent infringement, C.A. No. 3:07-cv-05017, C.A. No. 3:07-cv-05265, C.A. No. 3:07-cv-05136 and C.A. No. 3:07-cv-05001, respectively.

In October 2007, we received notification that the FDA had received an ANDA from Anchen Pharmaceuticals, Inc., or Anchen, seeking approval of a generic version of Schering-Plough's 2.5/120 mg tablets of CLARINEX-D 12 hour desloratadine and pseudoephedrine extended release tablets. Anchen's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable or not infringed by the generic version for which Anchen is seeking approval. In November 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Anchen for patent infringement, C.A. No. 07-cv-5737.

In September 2007, we received notification that the FDA had received an ANDA from Sandoz, Inc., or Sandoz, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Sandoz's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable, or are not infringed by the generic version for which Sandoz is seeking approval. In December 2007, we and the University of Massachusetts filed a civil action in the United States District Court for the District of New Jersey against Sandoz for patent infringement, C.A. No. 3:07-cv-04213.

In February 2008, we received notification that the FDA had received an ANDA from Belcher Pharmaceuticals, Inc., or Belcher, seeking approval of a generic version of Schering-Plough's 5 mg tablets of CLARINEX. Belcher's submission includes a Paragraph IV certification alleging that our patents listed by Schering-Plough (as licensee of such patents) in the Orange Book for CLARINEX are invalid, unenforceable, or are not infringed by the generic version for which Belcher is seeking approval. In February 2008, we and the University of Massachusetts filed a civil action in the United

States District Court for the District of New Jersey against Belcher for patent infringement, C.A. No. 3:08-cv-00945.

We believe that all of these ANDAs are subject to a statutory stay of approval until June 21, 2009 based on previous litigation commenced by Schering-Plough against these parties in separate civil actions involving another patent.

#### **BROVANA Patent Infringement Claim**

In April 2007, we were served with a Complaint filed in the United States District Court for the Southern District of New York, C.A. No. 1:07-cv-2353, by Dey, alleging that manufacture and sale of BROVANA® (arformoterol tartrate) Inhalation Solution infringes or will induce infringement of a single U.S. patent for which Dey owns all rights, title and interest. In April 2007, we filed an Answer and Counterclaim to this Complaint seeking to invalidate the originally asserted patent and a second related patent. In May 2007, Dey filed a reply asserting infringement of the second patent. Under the current trial scheduling order, trial will begin no earlier than January 12, 2009. It is too early to make a reasonable assessment as to the likely outcome or impact of this litigation. We are unable to reasonably estimate any possible range of loss or liability related to this lawsuit due to its uncertain resolution.

#### ***Stock Option Inquiry and Derivative Stockholder Complaints***

We announced in November 2007 that we had received notice from the SEC that the informal inquiry into our stock option grants and stock option granting practice had been completed and that no enforcement action was recommended.

From June to October 2006, six stockholder derivative complaints were commenced against us (as a nominal defendant) and certain of our current and former officers and directors. Three of these complaints were filed in the Superior Court, Middlesex County, Commonwealth of Massachusetts (later transferred to the Business Litigation Session of the Superior Court, Suffolk County, Commonwealth of Massachusetts) and three were filed in the United States District Court for the District of Massachusetts. All state court complaints were later consolidated into one state court action, and all Federal court complaints were consolidated into one Federal court action. It was alleged in both actions that the individual defendants breached their fiduciary duties and were unjustly enriched in connection with certain stock option grants; violations of Federal securities laws were alleged in the Federal action as well. The complaints sought monetary damages in unspecified amounts, equitable and injunctive relief, including disgorgement of profits obtained by certain defendants and other relief as determined by the court.

In October 2007, we reached a settlement with the parties to both the state and Federal action providing for the dismissal of both actions, subject to the approval of the court. The settlement resolves all claims and includes no finding of wrongdoing on the part of any of the defendants and no cash payment other than attorneys' fees. As part of the settlement, we implemented stock option grant and other procedures that reflect developing best practices. The settlement became final and effective in January 2008 upon final approval by the state court and entry of dismissal with prejudice by the Federal court.

#### ***Tecastemizole Class Action Complaints***

In June 2007, we filed in the United States District Court for the District of Massachusetts, or the Court, a Stipulation of Settlement regarding two securities class action lawsuits, or class actions, pending in the Court naming Sepracor and certain of our current and former officers and one director as defendants. The class actions, which were filed on behalf of certain purchasers of our equity and debt securities, or the plaintiffs, allege that the defendants violated the Federal securities laws by making false and misleading statements relating to the testing, safety and likelihood of approval of

tecstemizole by the FDA. The Stipulation of Settlement contains no admission of wrongdoing. Sepracor and the other defendants have always maintained and continue to believe that we did not engage in any wrongdoing or otherwise commit any violation of Federal or state securities laws or other laws. However, given the potential cost and burden of continued litigation, we believe the settlement was in our best interests and the best interests of our stockholders. Under the terms of the Stipulation of Settlement, in June 2007 we paid into escrow \$52.5 million in settlement of the class actions and, in July 2007, received an \$18.5 million reimbursement from our insurance carriers. We recorded the litigation settlement expense of \$34.0 million, relating to this matter, during the quarter ended March 31, 2007. In September 2007, the Court granted final approval of the Stipulation of Settlement and entered a final judgment consistent with the Stipulation of Settlement. The settlement is now final and the total settlement amount has been released from escrow. Pursuant to the final judgment entered by the Court, the Court dismissed the class actions with prejudice, and the plaintiffs are deemed to have released all claims against us.

#### ***LUNESTA Trademark Claim***

In September 2006, Tharos Laboratories, Inc., or Tharos, filed suit against us in the United States District Court, District of Utah, Central Division, 2:06-cv-00757, alleging trademark infringement, dilution, unfair competition, false advertising and false designation of origin arising out of our use of our silk luna moth design in connection with LUNESTA. Tharos sought unspecified monetary damages and to enjoin our use of the silk luna moth design. In October 2007, we reached a final agreement with Tharos, and the case has been dismissed.

#### ***Other Legal Proceedings***

From time to time we are party to other legal proceedings in the course of our business. We do not, however, expect such other legal proceedings to have a material adverse effect on our business, financial condition or results of operations.

#### **N) Stockholders' Equity (Deficit)**

##### **Preferred Stock**

Our board of directors is authorized, without stockholder approval, but subject to any limitations prescribed by law, to issue up to 1,000,000 shares of preferred stock, in one or more series. Each such series will have such rights, preferences, privileges and restrictions, including voting rights, dividend rights, conversion rights, redemption privileges and liquidation preferences, as will be determined by the board of directors.

##### **Treasury Stock**

In November 2005, we received 2,326,263 shares of our common stock upon the settlement of call spread options we purchased in December 2003. The shares are being held in treasury at cost and may be issued in connection with our employee stock purchase plan and other corporate purposes.

## Accumulated Other Comprehensive Income

The components of accumulated other comprehensive income at December 31, 2007 and 2006 were as follows:

	2007	2006
	(In Thousands)	
Net unrealized gains on securities available for sale . . . . .	\$ 5,416	\$ 990
Foreign currency translation . . . . .	4,771	1,850
Total . . . . .	<u>\$10,187</u>	<u>\$2,840</u>

### O) Stock Plans

We have stock-based compensation plans, which are described below. Effective January 1, 2006, we record the issuance of stock options using SFAS 123(R). Prior to January 1, 2006, we accounted for share-based compensation to employees in accordance with APB 25 and related interpretations and followed the disclosure requirements of SFAS 123.

The 1997 Stock Option Plan, or 1997 Plan, permitted us to grant non-qualified stock options, or NSOs, to purchase up to 1,000,000 shares of common stock to our employees and consultants. Executive officers were not entitled to receive stock options under the 1997 Plan. NSOs granted under the 1997 Plan have a maximum term of ten years from the date of grant and generally vest over five years. The 1997 Plan expired in the fourth quarter of 2007.

The 1999 Director Stock Option Plan, or 1999 Director Plan, permits us to grant NSOs to purchase up to 1,800,000 shares of common stock to our non-employee directors. Under the 1999 Director Plan, stock option grants for the purchase of 20,000 shares of our common stock are automatically made to each non-employee director upon his first election to the board of directors and, on the date of any annual meeting occurring at last six months after he is first elected to the board of directors if he is serving as a director at the adjournment of such annual meeting. Stock options granted under this plan, have a maximum term of ten years and an exercise price equal to the last reported sales price of our common stock on NASDAQ on the date of grant. The stock options to new directors typically vest in equal annual installments over five years and the annual grants typically vest in full on the day prior to the first annual meeting following the date of grant.

The 2000 Stock Incentive Plan, or 2000 Plan, permits us to grant incentive stock options, or ISOs, NSOs and restricted stock awards to purchase up to 13,500,000 shares of common stock to our employees, officers, directors and consultants. Stock options granted under the 2000 Plan have a maximum term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over five years. In May 2002, the stockholders approved an amendment to the 2000 Plan increasing the number of shares of common stock that could be granted under the 2000 Plan from 2,500,000 shares to 4,000,000 shares. In May 2003, the stockholders approved an amendment to the 2000 Plan increasing the number of shares of common stock that could be granted under the 2000 Plan from 4,000,000 shares to 5,500,000 shares. In May 2004, the stockholders approved an amendment to the 2000 Plan increasing the number of shares of common stock that could be granted under the 2000 Plan from 5,500,000 shares to 8,000,000 shares. In May 2005, the stockholders approved an amendment to the 2000 Plan increasing the number of shares of common stock that could be granted under the 2000 Plan from 8,000,000 shares to 9,500,000 shares. In May 2006, the stockholders approved an amendment to the 2000 Plan increasing the number of shares of common stock that could be granted under the 2000 Plan from 9,500,000 shares to 11,500,000 shares. In May 2007, our stockholders approved an amendment to the 2000 Plan increasing the number of shares of common stock that could be granted under the 2000 Plan from 11,500,000 shares to 13,500,000 shares.

The 2002 Stock Incentive Plan, or 2002 Plan, permits us to grant NSOs and restricted stock awards to purchase up to 4,000,000 shares of common stock to our employees, other than executive officers. Stock options granted under the 2002 Plan have a maximum term of ten years from the date of grant, have an exercise price not less than the fair value of the stock on the grant date and generally vest over five years. In June 2002, the Board of Directors approved an amendment to the 2002 Plan increasing the number of shares of common stock that may be granted under the 2002 Plan from 500,000 shares to 4,000,000 shares.

Stock options granted under the equity incentive plans are generally non-qualified stock options, but the equity incentive plans permit the granting of "incentive stock options" under the U.S. Internal Revenue Code of 1986, as amended, or the Code. The exercise price of a stock option generally is equal to the fair market value of our common stock on the option grant date. The contractual term of stock options granted under our equity incentive plans is generally 10 years.

Under the equity incentive plans, in addition to stock options, we granted certain employees restricted stock awards. Restricted stock awards are non-vested stock awards. Restricted stock awards are independent of stock option grants and are subject to forfeiture or repurchase if employment terminates prior to the release of the restrictions. Such awards generally vest annually over a two to five year period from the date of grant. Ownership of restricted stock typically cannot be transferred until the shares have vested. In connection with restricted stock grants, we record compensation expense based on the fair value of the shares granted. This stock compensation is being amortized on a straight-line basis over the vesting periods.

We issue common stock from previously authorized but unissued shares to satisfy stock option exercises, restricted stock grants and purchases under the 1998 ESPP.

Stock options and other equity awards, if any, outstanding under the 1997 Plan, the 1999 Director Plan, the 2000 Plan and the 2002 Plan vest and become fully exercisable upon a change in control of Sepracor.

The following table presents stock-based employee compensation expenses included in our consolidated statements of operations:

	Year Ended		
	December 31, 2007	December 31, 2006	December 31, 2005
	(In Thousands)		
Cost of products sold . . . . .	\$ 496	\$ 454	\$ —
Research and development . . . . .	9,470	10,984	—
Selling, marketing and distribution . . . . .	11,425	15,386	140
General and administrative . . . . .	12,887	18,376	904
Stock-based compensation expense . . . . .	<u>\$34,278</u>	<u>\$45,200</u>	<u>\$1,044</u>

The following table presents stock-based employee compensation expenses by type of award:

	Year Ended		
	December 31, 2007	December 31, 2006	December 31, 2005
	(In Thousands)		
Employee stock options . . . . .	\$27,695	\$41,385	\$1,044
Restricted stock . . . . .	5,104	1,930	—
Employee stock purchase plan . . . . .	1,479	1,885	—
Stock-based compensation expense . . . . .	<u>\$34,278</u>	<u>\$45,200</u>	<u>\$1,044</u>

The following tables summarize information about stock options outstanding at December 31, 2007 (in thousands, except for per share amounts and contractual life):

Range of Exercise Price Per Share	Options Outstanding			Options Exercisable	
	Number of Options Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighted-Average Exercise Price Per Share	Number of Options Exercisable	Weighted-Average Exercise Price Per Share
\$ 6.24 – \$ 8.31 .....	567	4.7	\$ 6.28	567	\$ 6.28
11.57 – 14.50 .....	884	3.5	13.03	765	12.78
18.45 – 27.15 .....	2,533	4.0	24.24	1,902	24.19
27.70 – 39.06 .....	396	5.4	34.80	215	35.40
44.15 – 64.50 .....	5,932	7.4	52.93	2,158	53.91
71.88 – 87.50 .....	119	2.5	85.27	119	85.27
\$ 6.24 – \$87.50 .....	<u>10,431</u>	6.0	\$39.73	<u>5,726</u>	\$33.78

2007				
	Number of Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Terms (In Years)	Aggregate Intrinsic Value (In Thousands)
Balance at January 1, .....	10,799	\$ 36.99(1)		
Granted .....	2,586	45.34		
Exercised .....	(1,360)	22.09		
Cancelled .....	(1,001)	48.86		
Expired .....	(593)	39.74		
Balance at December 31, .....	10,431	\$ 39.73	6.0	\$28,356
Options exercisable at December 31, .....	5,726	\$ 33.78	4.0	\$25,805
Vested and unvested expected to vest at December 31, .....	9,834	\$ 39.37	5.8	\$28,163
Weighted-average fair value of options granted during the year December 31, ..	\$15.84			

(1) In March 2007, the exercise price of certain stock options was increased at the election of the officers holding such options.

All stock options granted during the years ended December 31, 2007, 2006 and 2005 were granted with exercise prices equal to the fair market value of our common stock on the grant date.

The total intrinsic value of stock options exercised during the year ended December 31, 2007 and 2006 was \$33.6 million and \$48.2 million, respectively.

Our non-vested share activity for the year ended December 31, 2007 was as follows:

	Stock Options		Restricted Stock	
	Number of Shares (In Thousands)	Weighted Average Fair Value	Number of Shares (In Thousands)	Weighted Average Fair Value
Non-vested at December 31, 2006 .....	4,544	\$22.65	174	\$55.34
Granted .....	2,586	15.84	418	41.03
Vested .....	(1,424)	19.33	(46)	55.24
Forfeited .....	(1,001)	23.22	(44)	53.53
Non-vested at December 31, 2007 .....	<u>4,705</u>	\$18.91	<u>502</u>	\$41.94



At December 31, 2006 the weighted average fair value of stock options granted and stock options vested was \$19.86 and \$18.47, respectively.

At December 31, 2007, unrecognized compensation expense related to non-vested stock options and restricted stock was \$76.1 million and \$17.4 million, respectively, which is expected to be recognized over weighted average periods of 3.1 years and 3.0 years, respectively.

There were approximately 4,043,000 shares available under our stock plans for future option and restricted stock grants as of December 31, 2007.

The 1998 Employee Stock Purchase Plan, or 1998 ESPP, permits an aggregate of 1,400,000 shares of common stock to be purchased by employees at 85% of market value on the first or last day of each six-month offering period, whichever is lower, through accumulation of payroll deductions ranging from 1% to 10% of compensation as defined, subject to certain limitations. Employees purchased approximately 207,000, 167,000 and 160,000 shares for a total of \$6.0 million, \$7.3 million and \$6.7 million during the years ended December 31, 2007, 2006 and 2005, respectively. In May 2003, our stockholders approved an amendment to the 1998 ESPP increasing the number of shares of common stock authorized for issuance under the 1998 ESPP from 600,000 shares to 900,000 shares. In May 2006, our stockholders approved an amendment to the 1998 ESPP increasing the number of shares of common stock authorized for issuance under the 1998 ESPP from 900,000 shares to 1,400,000 shares. At December 31, 2007, there were approximately 241,000 shares of common stock authorized for future issuance under the 1998 ESPP.

At December 31, 2007, the estimated unrecognized compensation expense related to the December 1, 2007 offering period of the 1998 ESPP, which concludes on May 31, 2008, was \$574,000. The associated expense is amortized on a straight-line basis over the offering period.

#### P) Income Taxes

The components of income tax expense consist of the following at December 31:

	2007	2006	2005
	(In Thousands)		
Current income tax expense			
Federal .....	\$ 19,764	\$3,530	\$ —
State .....	2,940	126	38
Foreign .....	686	—	113
Total current income tax expense .....	<u>\$ 23,390</u>	<u>\$3,656</u>	<u>\$151</u>
Deferred income tax expense			
Federal .....	\$(15,376)	\$ —	\$ —
State .....	(1,744)	—	—
Foreign .....	—	—	—
Total deferred income tax benefit .....	<u>\$(17,120)</u>	<u>\$ —</u>	<u>\$ —</u>
Total current and deferred income tax expense .....	<u>\$ 6,270</u>	<u>\$3,656</u>	<u>\$151</u>

For each of the years ended December 31, 2007, 2006 and 2005, our United States Federal statutory tax rate was 35%, 34% and 34% and our effective tax rate was 9.7%, 2.1% and (1.0)%,

respectively. Our effective tax rate varies from our statutory tax rate for the years ended December 31 principally due to the following:

	2007	2006 (as restated)	2005 (as restated)
United States Federal statutory tax rate . . . . .	35.0%	34.0%	34.0%
State income taxes, net of U.S. Federal tax expense .	4.9	5.9	(0.2)
Tax rate and tax law differential of foreign operations . . . . .	0.9	—	(7.8)
Research and development credits . . . . .	(11.4)	(4.4)	32.7
Change in valuation allowance . . . . .	(24.5)	(35.3)	(60.7)
Other nondeductible expenses . . . . .	0.3	0.4	1.0
Deferred compensation amortization . . . . .	4.5	1.5	—
	<u>9.7%</u>	<u>2.1%</u>	<u>(1.0)%</u>

Deferred tax assets and liabilities are recognized for the estimated future tax consequences attributable to tax benefit carryforwards and to differences between the financial statement amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates in effect for the year in which the differences are expected to reverse. A valuation allowance is established if, based on management's review of both positive and negative evidence, it is more likely than not that all or a portion of the deferred tax asset will not be realized. The possible adverse impact to our XOPENEX Inhalation Solution sales if an "at risk" generic launch were to occur or we are unable to successfully defend our patent rights and increased sales and marketing expenses as a result of the expected commercial introduction of Omnaris AQ in the first half of 2008 and the expected commercial introduction ALVESCO HFA in the second half of 2008, management continues to conclude a valuation allowance is required for the full amount of the deferred tax asset. Of our total valuation allowance of \$662.1 million, approximately \$152.2 million relates to stock option compensation deductions. The tax benefit associated with the stock option compensation deductions will be credited to equity if realized. If in the future, we determine based on expected profitability, that these deferred tax assets are more likely than not to be realized, a release of all, or part, of the related valuation allowance could result in an immediate material income tax benefit in the period of decrease and material income tax provisions in future periods. Such release of the valuation allowance could occur within the next 12 months upon resolution of the aforementioned uncertainties.

At December 31, 2007, we had Federal tax net operating loss carryforwards of approximately \$1.0 billion, which expire in the years 2020 through 2025 and state tax net operating loss carryforwards of approximately \$491.7 million, which expire in the years 2008 through 2025. Based upon the Internal Revenue Code and changes in company ownership, utilization of the net operating losses and tax credit carryforwards may be subject to an annual limitation. At December 31, 2007, we had Netherlands Antilles net operating loss carryforwards of approximately \$5.7 million, which will expire in the years 2008 through 2012. At December 31, 2007, we had Federal and state research and experimentation credit carryforwards of approximately \$60.7 million and \$35.2 million, respectively, which will expire from now through 2027 and 2022, respectively. We also have Canadian federal investment tax credits of \$5.6 million, which expire in the years 2009 through 2027.

The components of net deferred taxes were as follows at December 31:

	2007	2006 (as restated)
	(In Thousands)	
<b>Assets</b>		
Net operating loss carryforwards . . . . .	\$ 379,516	\$ 453,388
Research and development capitalization . . . . .	24,161	32,445
Research and experimentation tax credit carryforwards . . . . .	93,984	98,305
Accrued expenses . . . . .	10,968	29,721
Reserves . . . . .	92,472	68,135
Depreciation . . . . .	2,592	1,082
Intangibles . . . . .	1,664	8,333
Other . . . . .	8,112	4,248
License fee . . . . .	29,227	—
Stock based compensation . . . . .	15,351	—
Basis difference of subsidiaries . . . . .	4,118	—
<b>Liabilities</b>		
Deferred revenue on license fees . . . . .	(103)	—
Basis difference of subsidiaries . . . . .	—	(144)
Valuation allowance . . . . .	(662,062)	(695,513)
<b>Net deferred taxes . . . . .</b>	<b>\$ —</b>	<b>\$ —</b>

The United States and foreign components of income before income taxes were as follows for the years ended December 31:

	2007	2006 (as restated)	2005 (as restated)
	(In Thousands)		
United States . . . . .	\$69,463	\$178,617	\$(11,552)
Foreign . . . . .	(4,860)	(3,800)	(4,190)
<b>Total . . . . .</b>	<b>\$64,603</b>	<b>\$174,817</b>	<b>\$(15,742)</b>

We file tax returns in the U.S. Federal jurisdiction and in various state, local and foreign jurisdictions. During the third quarter of 2007, the Internal Revenue Service formally concluded its examination of our 2004 and 2005 federal income tax returns, and no payment was due as a result of the audit. We are no longer subject to IRS examination for years prior to 2004, although carryforward attributes that were generated prior to 2004 may still be adjusted upon examination by the IRS if they either have been or will be used in a future period. We receive inquiries from various states during the year, some of those inquiries include an audit of state returns previously filed. With limited exceptions, we are no longer subject to state or local examinations for years prior to 2003, however, carryforward attributes that were generated prior to 2003 may still be adjusted upon examination by state or local tax authorities if they either have been or will be used in a future period.

The foreign jurisdictions where we currently file income tax returns are Canada and the Netherlands Antilles. We are currently under examination by Canada Revenue Agency, or CRA, for our Scientific Research and Experimental Development claims for the years ended December 31, 2006, 2005, 2004 and 2003. There are currently no examinations being conducted by the tax authorities in the Netherlands Antilles. With limited exceptions, we are no longer subject to examination in Canada and the Netherlands Antilles for years prior to 2003, although carryforward attributes that were generated prior to these periods may still be adjusted upon examination if they either have been or will be used in a future period. United States Federal income taxes were not provided on permanently reinvested undistributed earnings for certain non-U.S. subsidiaries of approximately \$2.3 million as of December 31, 2007. We will reinvest these earnings indefinitely in its operations outside the United States. We have deemed it impracticable to determine the amount of taxes payable if any monies were to be returned to us in the United States.

Effective January 1, 2007, we adopted the provisions of FIN 48, *Accounting for Uncertainty in Income Taxes*. The implementation of FIN 48 did not have a material impact on our consolidated financial statements or results of operations. A reconciliation of the beginning and ending amount of unrecognized tax benefits is as follows (in thousands):

Balance at January 1, 2007 . . . . .	\$ —
Additions based on tax positions related to the current year . . . . .	—
Additions for tax positions of prior years . . . . .	18,438
Reductions for tax positions of prior years . . . . .	—
Settlements . . . . .	—
Balance at December 31, 2007 . . . . .	<u>\$18,438</u>

The \$18.4 million of unrecognized tax benefits represents tax positions for which the ultimate deductibility is highly certain but for which there is uncertainty about the timing of such deduction. Because of the impact of deferred income tax accounting, other than for interest and penalties, the disallowance of the shorter deductibility period would not change the effective income tax rate but would accelerate the payment of cash to the taxing authority to an earlier period by approximately \$1.3 million.

We recognize accrued interest and penalties related to unrecognized tax benefits as a component of tax expense. This policy did not change as a result of the adoption of FIN 48. As of December 31, 2007, we have accrued \$210,000 of interest and \$0 of penalties.

We are still in the process of completing a research and development study and it is reasonably possible that our gross unrecognized tax benefits balance may change within the next twelve months. However, at this time an estimate of the range cannot be made.

#### **Q) Employees' Savings Plan**

We have a 401(k) savings plan for all domestic employees. Under the provisions of our 401(k) savings plan, employees may voluntarily contribute up to 60% of their compensation, up to the statutory limit. In addition, we can make a matching contribution at our discretion. We matched 50% of the first \$7,000, \$5,000 and \$4,000 contributed by employees up to \$3,500, \$2,500 and \$2,000 maximum per employee during 2007, 2006 and 2005, respectively. We incurred expenses of \$5.4 million, \$3.9 million, and \$2.3 million in 2007, 2006 and 2005, respectively, as a result of our matching contribution.

#### **R) Restructuring Charges**

During the quarter ended December 31, 2007, we completed an evaluation of our sales force structure, size and allocation that was initiated in the second quarter of 2007 in an attempt to maximize efficiency of our sales force. This evaluation resulted in a decision to restructure and re-align our sales force. The restructuring program was completed by December 31, 2007 and approximately 300 positions were eliminated. All associated costs are expected to be paid out by the end of the second quarter of 2008.

The following table sets forth the restructuring accrual activity during the years ended December 31, 2007 and 2006:

	Employee Related Items and Benefits	Contract Terminations	Total
	(In Thousands)		
Restructuring charges accrual at December 31, 2006 .....	\$ —	\$ —	\$ —
Initial provision .....	6,493	428	6,921
Cash payments .....	(187)	—	(187)
Restructuring charges accrual at December 31, 2007 .....	<u>\$6,306</u>	<u>\$428</u>	<u>\$6,734</u>

The restructuring reserve is recorded as other current liabilities on our balance sheet.

The employee related items and benefits primarily relate to severance costs for the employees that were terminated. The contract terminations consist of excess leased computer equipment and company cars as a result of the sales force reduction.

#### S) Business Segment and Geographic Area Information

We operate in one business segment, which is the discovery, research and development and commercialization of pharmaceutical products.

All of our revenues in 2007, 2006 and 2005 were received from unaffiliated customers located in the United States or its territories. Product revenue by product is presented below:

	2007	2006 (as restated)	2005 (as restated)
	(In Thousands)		
Product sales:			
XOPENEX Inhalation Solution .....	\$ 487,189	\$ 542,944	\$410,807
LUNESTA .....	600,904	565,436	327,100
XOPENEX HFA .....	74,883	40,994	11,958
BROVANA .....	14,280	—	—
Total product sales .....	<u>\$1,177,256</u>	<u>\$1,149,374</u>	<u>\$749,865</u>

Long-lived asset information, which is comprised of property and equipment, by geographic area is presented below:

	2007	2006	2005
	(In Thousands)		
Long-lived assets:			
United States .....	\$75,151	\$64,156	\$63,663
Canada .....	12,157	8,655	8,804
Total long-lived assets .....	<u>\$87,308</u>	<u>\$72,811</u>	<u>\$72,467</u>

**T) Quarterly Consolidated Financial Data (Unaudited)**

	For the Quarter Ended			
	March 31, 2007 (as restated)(1)	June 30, 2007 (as restated)(1)	September 30, 2007 (as restated)(1)	December 31, 2007(4)
	(In Thousands, Except Per Share Data)			
Net revenues	\$327,700	\$276,792	\$280,758	\$339,980
Gross profit	\$296,082	\$251,262	\$254,338	\$306,393
Net income (loss) applicable to common shares	\$ 18,815	\$ 4,811	\$ 39,708	\$ (5,001)
Basic net income (loss) per common share	\$ 0.18	\$ 0.05	\$ 0.37	\$ (0.05)
Diluted net income (loss) per common share	\$ 0.16	\$ 0.04	\$ 0.34	\$ (0.05)

	For the Quarter Ended			
	March 31, 2006 (as restated)(1)	June 30, 2006 (as restated)(1)(3)	September 30, 2006 (as restated)(1)(2)	December 31, 2006 (as restated)(1)
	(In Thousands, Except Per Share Data)			
Net revenues	\$281,354	\$261,687	\$286,830	\$353,263
Gross profit	\$255,662	\$240,711	\$261,949	\$320,076
Net income applicable to common shares	\$ 5,712	\$ 8,325	\$ 61,965	\$ 95,158
Basic net income per common share	\$ 0.05	\$ 0.08	\$ 0.59	\$ 0.90
Diluted net income per common share	\$ 0.05	\$ 0.07	\$ 0.54	\$ 0.82

(1) See Note U "Restatement of Financial Statements Based on Review of Government Pricing" below.

The following table sets forth the impact of the product sales reduction on our historical financial statements disclosed in the Quarterly Consolidated Financial Data table, set forth above, for our fiscal quarters ended March 31, June 30 and September 30, 2007 and 2006, and December 31, 2006.

	For the Quarter Ended		
	March 31, 2007	June 30, 2007	September 30, 2007
	(In Thousands, Except Per Share Data) (unaudited)		
Net revenues			
As previously reported	\$331,434	\$278,128	\$283,945
As restated	\$327,700	\$276,792	\$280,758
Gross profit			
As previously reported	\$299,816	\$252,598	\$257,525
As restated	\$296,082	\$251,262	\$254,338
Net income applicable to common shares			
As previously reported	\$ 22,549	\$ 6,147	\$ 42,895
As restated	\$ 18,815	\$ 4,811	\$ 39,708
Basic net income per common share			
As previously reported	\$ 0.21	\$ 0.06	\$ 0.40
As restated	\$ 0.18	\$ 0.05	\$ 0.37
Diluted net income per common share			
As previously reported	\$ 0.19	\$ 0.05	\$ 0.37
As restated	\$ 0.16	\$ 0.04	\$ 0.34

	For the Quarter Ended			
	March 31, 2006	June 30, 2006	September 30, 2006	December 31, 2006
	(In Thousands, Except Per Share Data)			
	(unaudited)			
Net revenues				
As previously reported	\$285,678	\$264,406	\$289,296	\$357,155
As restated	\$281,354	\$261,687	\$286,830	\$353,263
Gross profit				
As previously reported	\$259,986	\$243,430	\$264,415	\$323,968
As restated	\$255,662	\$240,711	\$261,949	\$320,076
Net income applicable to common shares				
As previously reported	\$ 10,036	\$ 11,044	\$ 64,431	\$ 99,050
As restated	\$ 5,712	\$ 8,325	\$ 61,965	\$ 95,158
Basic net income per common share				
As previously reported	\$ 0.10	\$ 0.11	\$ 0.61	\$ 0.94
As restated	\$ 0.05	\$ 0.08	\$ 0.59	\$ 0.90
Diluted net income common share				
As previously reported	\$ 0.09	\$ 0.10	\$ 0.56	\$ 0.85
As restated	\$ 0.05	\$ 0.07	\$ 0.54	\$ 0.82

- (2) The three months ended September 30, 2006 includes an \$8.3 million product sales allowances and reserve reversal related to rebates under the Department of Veterans Affairs TRICARE Pharmacy Benefits Program, which were based on a U.S. Federal Court of Appeals ruling in September 2006 that pharmaceutical manufacturers are not required to reimburse on drugs purchased through the TRICARE Program
- (3) The three months ended June 30, 2006 includes a \$3.0 million Medicaid product sales allowances and reserve reversal as a result of our review of a prior period rebate per unit calculation resulting in a reserve reversal of a prior period estimate.
- (4) The three months ended December 31, 2007 includes a \$75.0 million research and development expense associated with our Bial license agreement.

#### U) Restatement of Financial Statements Based on Review of Government Pricing

Subsequent to the filing of our Annual Report on Form 10-K for the fiscal year ended December 31, 2006, we concluded that based on our review of our government price reporting, we would need to restate our financial statements.

Revenue is recognized for amounts that are fixed or determinable assuming all other applicable criteria are met. We recently determined that PHS discounts were provided to non-PHS covered entities. This circumstance creates uncertainty as to whether a new best price was set in prior periods. If a new best price was set, additional Medicaid rebates will be required to be paid. A portion of the revenue we previously recognized is therefore contingent on the outcome of this matter. Revenue has been reduced and rebate liabilities increased to adjust for the amounts previously invoiced and received that are contingent and do not qualify for revenue recognition. The restatement for such contingent amounts reflects our best estimate of the net revenue that should have been recognized in the respective periods.

Under the Medicaid rebate program, we are obligated to pay a rebate to each participating State Medicaid program for each unit of product reimbursed by Medicaid. The amount of the rebate is set by law as the greater of (a) 15.1% of the average manufacturer price, which is referred to as AMP, or (b) the difference between AMP and the Medicaid best price, which is the lowest price available from

us to any customer not excluded by law from that determination. The determination of whether a new best price was set is uncertain and is a matter of judgment that will be subject to disclosure to CMS. A determination of the actual amount of payments required may change as a result of future interactions with CMS and we cannot be certain that we will not be subject to fines, penalties and interest.

We also excluded transactions involving the Pennsylvania General Assistance Program, or PAGA, from our calculation of the Medicaid best price based on the belief that PAGA, a State Pharmaceutical Assistance Program, was excluded from Medicaid best price. Despite review of available materials, we cannot be sure that PAGA is excluded from Medicaid best price. While we may have incorrectly excluded the PAGA transactions, we do not believe including the transactions would have set the Medicaid best price for any period in which the PHS price was given to an entity that was not a PHS covered entity, where the PHS price was lower than the PAGA price and the PHS price is determined to be included in best price. We notified the Centers for Medicare and Medicaid Services, or CMS, of these possible PHS and PAGA errors in January 2008.

The aggregate amount by which we have reduced revenue for contingent rebates in prior periods is approximately \$60.2 million. The amount by which we have reduced revenues for the fiscal years ended December 31, 2006 and 2005 is approximately \$13.4 million and \$19.8 million, respectively.

The following tables set forth the effects of the restatement on certain line items within our consolidated statement of operations and comprehensive income (loss) for the years ended December 31, 2006 and 2005 and consolidated balance sheet as of December 31, 2006.

	Year Ended December 31,	
	2006	2005
	(In Thousands, Except Per Share Data)	
Consolidated Statement of Operations changes:		
Product sales		
As previously reported . . . . .	\$1,162,775	\$769,685
As restated . . . . .	\$1,149,374	\$749,865
Income (loss) from operations		
As previously reported . . . . .	\$ 164,517	\$(17,617)
As restated . . . . .	\$ 151,116	\$(37,437)
Income (loss) before income taxes		
As previously reported . . . . .	\$ 188,218	\$ 4,078
As restated . . . . .	\$ 174,817	\$(15,742)
Net income (loss)		
As previously reported . . . . .	\$ 184,562	\$ 3,927
As restated . . . . .	\$ 171,161	\$(15,893)
Basic net income (loss) per common share		
As previously reported . . . . .	\$ 1.76	\$ 0.04
As restated . . . . .	\$ 1.63	\$ (0.15)
Diluted net income (loss) per common share		
As previously reported . . . . .	\$ 1.60	\$ 0.03
As restated . . . . .	\$ 1.48	\$ (0.15)



	As of December 31, 2006 (in thousands)
Consolidated Balance Sheet changes:	
Product sales allowances and reserves	
As previously reported . . . . .	\$115,647
As restated . . . . .	\$167,631
Accumulated deficit	
As previously reported . . . . .	\$ 92,168
As restated . . . . .	\$ 40,184

The amounts by which have reduced revenues were based on managements best estimates and assumptions made prior to any concurrence by CMS. These amounts may change as a result of future communications with CMS, and we cannot be certain that we have not overestimated the amount of additional rebates we may be required to pay, that the amount of any additional rebate payments or other payments we may owe will not exceed our current estimates or that we will not be subject to fines, penalties or interest. In addition, both the federal government and state governments have initiated investigations and lawsuits concerning the Medicaid price reporting practices of many pharmaceutical companies to ensure compliance with the Medicaid rebate program. As a result of the possible errors that we identified in our calculation of Medicaid rebate reserve amounts, we may face an increased risk of a government investigation or lawsuits concerning our Medicaid or other price reporting. If any such investigation or lawsuit is initiated we may be subject to fines and other penalties.

We have amended Notes B, P, S, and T and the Selected Financial Data appearing herein to reflect the effects of the matters discussed in this Note U.

#### **V) Subsequent Event**

In January 2008, we entered into an agreement with Nycomed GmbH, or Nycomed, for the exclusive U.S. distribution, development and commercialization in the United States, its territories and possessions of Nycomed's compound ciclesonide, and products incorporating such compound, including ALVESCO HFA Inhalation Aerosol metered-dose inhaler, for use in the treatment of asthma, and OMNARIS AQ nasal spray, for use in the treatment of allergic rhinitis. Under the agreement, we paid Nycomed an upfront payment of \$150.0 million in February 2008 and may be required to make subsequent payments of up to \$280.0 million over the life of the agreement upon accomplishment of various development and sales milestones. Nycomed will also receive compensation for supplying finished product pursuant to the agreement, including a supply price for the products, which will be based on Nycomed's manufacturing costs plus a percentage of such costs, and quarterly royalty payments based on our net sales of the products.

**SEPRACOR INC.**  
**Schedule II**  
**Valuation and Qualifying Accounts and Reserves**  
**Years Ended December 31, 2007, 2006 and 2005**  
**(In Thousands)**

<u>Description</u>	<u>Balance at Beginning of Period</u>	<u>Additions</u>	<u>Deductions</u>	<u>Balance at End of Period</u>
Allowance for Doubtful Accounts(1)				
Year Ended December 31, 2007 . . . . .	\$ 470	\$ —	\$ 11	\$ 459
Year Ended December 31, 2006 . . . . .	\$ 470	\$ —	\$ —	\$ 470
Year Ended December 31, 2005 . . . . .	\$ 510	\$ —	\$ 40	\$ 470

(1) Additions to Allowance for Doubtful Accounts are recorded as an expense.

Sales Rebates, Chargebacks & Allowances(2)				
Year Ended December 31, 2007 . . . . .	\$144,413	\$355,666	\$278,591	\$221,488
Year Ended December 31, 2006 (as restated) .	\$ 96,099	\$236,470	\$188,156	\$144,413
Year Ended December 31, 2005 (as restated) .	\$ 50,877	\$120,374	\$ 75,152	\$ 96,099

(2) Additions to Sales Rebates, Chargebacks and Allowances are recorded as a reduction of revenue.

Sales Return Reserves(3)				
Year Ended December 31, 2007 . . . . .	\$ 23,218	\$ 29,606	\$ 28,473	\$ 24,351
Year Ended December 31, 2006 . . . . .	\$ 16,269	\$ 20,253	\$ 13,304	\$ 23,218
Year Ended December 31, 2005 . . . . .	\$ 8,654	\$ 21,830	\$ 14,215	\$ 16,269

(3) Additions to Sales Return Reserves are recorded as a reduction of revenue.

Deferred Tax Asset Valuation Allowance(4)				
Year Ended December 31, 2007 . . . . .	\$695,513	\$135,223	\$168,674	\$662,062
Year Ended December 31, 2006 (as restated).	\$737,983	\$ 5,442	\$ 47,912	\$695,513
Year Ended December 31, 2005 (as restated).	\$680,665	\$ 66,365	\$ 9,047	\$737,983

(4) Additions to Deferred Tax Asset Valuation Allowance are recorded as expense.

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# EXHIBIT INDEX

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
3.1	Restated Certificate of Incorporation	Form 10-K for 12/31/2002	3.1	3/31/2003	000-19410
3.2	Amended and Restated By-Laws of the Registrant	Form 10-K for 12/31/2000	3.2	3/28/2001	000-19410
4.1	Specimen Certificate for shares of common stock, \$0.10 par value, of the Registrant	Form S-1	4.1	9/20/1991	333-41653
4.2	Rights Agreement, dated June 30, 2002, between the Registrant and EquiServe Trust Company, N.A., as Rights Agent	Form 8-K	4.1	6/4/2002	000-19410
4.3	Form of 0% Series A Convertible Subordinated Notes due 2008	Form 10-K for 12/31/2003	4.5	3/15/2004	000-19410
4.4	Form of 0% Series B Convertible Subordinated Notes due 2010	Form 10-K for 12/31/2003	4.6	3/15/2004	000-19410
4.5	Form of 0% Convertible Senior Subordinated Notes due 2024	Form 10-K for 12/31/2004	4.7	3/15/2004	000-19410
10.1#	The Registrant's 1991 Amended and Restated Stock Option Plan	Form 10-Q for 9/30/1999	10.1	11/12/1999	000-19410
10.2#	The Registrant's 1991 Director Stock Option Plan, as amended and restated	Form 10-K for 12/31/1998	10.3	3/31/1999	000-19410
10.3#	The Registrant's 1997 Stock Option Plan	Form 10-K for 12/31/1997	10.36	3/31/1998	000-19410
10.4#	The Registrant's 1998 Employee Stock Purchase Plan, as amended	Form 10-K for 12/31/2003	10.5	3/15/2004	000-19410
10.5#	The Registrant's 1999 Director Stock Option Plan	Form 10-Q for 9/30/1999	10.2	11/12/1999	000-19410
10.6#	The Registrant's 2000 Stock Incentive Plan, as amended	Form 10-Q for 6/30/2006	10.1	8/14/2006	000-19410
10.7#	The Registrant's 2002 Stock Incentive Plan, as amended	Form 10-Q for 6/30/2002	10.1	8/14/2004	000-19410
10.8	Form of Incentive Stock Option Agreement Granted under the Registrant's 2000 Stock Incentive Plan	Form 10-K for 12/31/2004	10.42	3/16/2005	000-19410
10.9	Form of Nonstatutory Stock Option Agreement Granted under the Registrant's 2000 Stock Incentive Plan	Form 10-K for 12/31/2004	10.43	3/16/2005	000-19410
10.10	Form of Restricted Stock Agreement Granted under the Registrant's 2000 Stock Incentive Plan	Form 10-K for 12/31/2006	10.35	3/1/2007	000-19410
10.11#	Summary of Plan regarding "Parachute Payments" and Section 280G Gross-Up Payments	Form 10-K for 12/31/1999	10.35	3/30/2000	000-19410
10.12#	Letter Agreement, dated June 10, 1994, between the Registrant and David Southwell	Form 10-K for 12/31/1994	—	—	000-19410
10.13#	Letter Agreement, dated February 23, 1995, between the Registrant and Robert F. Scumaci	Form 10-K for 12/31/1996	10.15	3/31/1997	000-19410
10.14#	Letter Agreement, dated March 11, 2003, between the Registrant and Mark H.N. Corrigan, M.D.	Form 10-Q for 3/31/2003	10.1	5/14/2003	000-19410
10.15#	Executive Retention Agreement, made as of February 1, 2002, by and between the Registrant and Timothy J. Barberich	Form 10-K for 12/31/2005	10.41	3/16/2006	000-19410
10.16#	Form of Executive Retention Agreement by and between the Registrant and each of David P. Southwell, Robert F. Scumaci, and Mark H.N. Corrigan	Form 10-K for 12/31/2005	10.42	3/16/2006	000-19410

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.17#	Employment Agreement by and between the Registrant and Adrian Adams dated March 1, 2007	Form 10-Q for 3/31/2007	10.1	5/10/2007	000-19410
10.18#	Executive Retention Agreement by and between the Registrant and Adrian Adams dated March 1, 2007	Form 10-Q for 3/31/2007	10.2	5/10/2007	000-19410
10.19#	Employment Agreement by and between the Registrant and Andrew I. Koven dated March 1, 2007	Form 10-Q for 3/31/2007	10.3	5/10/2007	000-19410
10.20#	Executive Retention Agreement by and between the Registrant and Andrew I. Koven dated March 1, 2007	Form 10-Q for 3/31/2007	10.4	5/10/2007	000-19410
10.21#	Amended and Restated Transition and Severance Agreement by and between the Registrant and W. James O'Shea dated September 7, 2007	Form 10-Q for 9/30/2007	10.1	11/09/2007	000-19410
10.22#	Employment Agreement by and between the Registrant and Mark Iwicki dated October 15, 2007	Form 10-Q for 9/30/2007	10.2	11/09/2007	000-19410
10.23#	Executive Retention Agreement by and between the Registrant and Mark Iwicki dated October 15, 2007	Form 10-Q for 9/30/2007	10.3	11/09/2007	000-19410
10.24#	Executive Retirement Agreement by and between Sepracor Inc. and Timothy Barberich dated December 27, 2007	Form 8-K for 12/27/2007	10.1	12/31/2007	000-19410
10.25	Lease as to Marlboro Industrial Park, dated December 12, 1995, between Valerie A. Colbert, Trustee of Second Marlboro Development Trust under Declaration of Trust dated September 15, 1972, and the Registrant (the "Marlboro Lease")	Form 10-K for 12/31/1995	—	—	000-19410
10.26	First Amendment to Marlboro Lease, dated February 1, 1997, and Second Amendment to Marlboro Lease, dated July 1, 1997	Form 10-K for 12/31/1997	10.22	3/31/1998	000-19410
10.27	Technology Transfer and License Agreement, dated as of January 1, 1994, between the Registrant and BioSeptra Inc.	Form 10-K for 12/31/1998	10.10	3/31/1999	000-19410
10.28	Technology Transfer and License Agreement, dated as of January 1, 1994, between the Registrant and HemaSure Inc.	Form 10-K for 12/31/1998	10.11	3/31/1999	000-19410
10.29†	Agreement, dated as of December 5, 1997, by and between the Registrant and Schering-Plough Ltd.	Form 10-K for 12/31/1997	10.31	3/31/1998	000-19410
10.30	Assignment Agreement, dated as of August 25, 1999, by and between the Registrant and Georgetown University	Form 10-Q for 9/30/1999	10.3	11/12/1999	000-19410
10.31†	License Agreement, dated August 31, 1999, by and between the Registrant and Hoechst Marion Roussel, Inc.	Form 10-K for 12/31/1999	10.30	3/30/2000	000-19410
10.32†	EX-US License Agreement, dated August 31, 1999, by and between the Registrant and Hoechst Marion Roussel, Inc.	Form 10-K for 12/31/1999	10.31	3/30/2000	000-19410
10.33†	License and Assignment Agreement, dated September 30, 1999, by and between the Registrant and Rhone-Poulenc Rorer SA	Form 10-K for 12/31/1999	10.32	3/30/2000	000-19410
10.34†	License Agreement, dated May 27, 1999, by and between UCB Farchim S.A. and the Registrant	Form 10-K for 12/31/1999	10.33	3/30/2000	000-19410

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
10.35†	Agreement, dated December 20, 2001, between Minnesota Mining and Manufacture Company, 3M Innovative Properties Company and the Registrant	Form 10-K for 12/31/2001	10.43	4/1/2002	000-19410
10.36	Indenture, dated as of December 12, 2003, by and between the Registrant and the JPMorgan Chase Bank, as Trustee	Form 8-K	4.1	12/19/2003	000-19410
10.37	Indenture, dated September 22, 2004, between the Registrant and JPMorgan Chase Bank, as trustee	Form 8-K	4.1	9/24/2004	000-19410
10.38†	Manufacturing Services Agreement, dated March 1, 2004, between Patheon and the Registrant	Form 8-K	99.1	12/21/2004	000-19410
10.39†	Amendments No. 1, 2 and 3 to the Manufacturing Services Agreement, dated March 1, 2004, between Patheon and the Registrant	Form 10-K for 12/31/2006	10.30	3/1/2007	000-19410
10.40†	Amended and Restated Manufacturing Services Agreement dated November 6, 2007 among the Registrant and Patheon Inc., Patheon Pharmaceuticals Inc. & MOVA Pharmaceutical Corporation	*			
10.41†	Exclusive Supply and Distribution Agreement, dated as of November 16, 2004, by and among 3M Company, through its 3M Drug Delivery Systems Division, 3M Innovative Properties Company and the Registrant	Form 10-K for 12/31/2004	10.46	3/16/2005	000-19410
10.42†	U.S. License Agreement for Levoceterizine, dated as of February 17, 2006, by and between UCB S.A. and the Registrant	Form 10-K for 12/31/2005	10.43	3/16/2006	000-19410
10.43†	Letter Agreement dated December 31, 2007, between the Registrant and Bial—Portela & C <sup>a</sup> , S.A.	*			
10.44†	License Agreement dated December 31, 2007, between the Registrant and Bial—Portela & C <sup>a</sup> , S.A.	*			
10.45†	Distribution and Development Agreement for Ciclesonide in the USA dated January 25, 2008 between the Registrant and Nycomed GmbH	*			
10.46†	Development, License and Commercialization Agreement dated September 11, 2007 by and between the Registrant and Glaxo Group Limited, an affiliate of GlaxoSmithKline	Form 10-Q for 9/30/2007	10.4	11/09/2007	000-19410
10.47#	Summary of Executive Officer Compensation for 2008	*			
10.48#	Summary of Non-Employee Director Compensation for 2008	*			
21	Subsidiaries of the Company	*			
23	Consent of PricewaterhouseCoopers LLP, an Independent Registered Public Accounting Firm	*			
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	*			
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/Rule 15d-14(a) of the Securities Exchange Act of 1934, as amended	*			

Exhibit Number	Description	Form or Schedule	Incorporated by Reference to		
			Exhibit No.	Filing Date with SEC	SEC File Number
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	*			
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	*			

\* Filed herewith.

- (#) Management contract or compensatory plan or arrangement filed as an exhibit to this Form pursuant to Item 14(c) of Form 10-K.
- (†) Confidential treatment has been requested as to certain portions, which portions have been filed separately with the Securities and Exchange Commission.

**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (Nos. 33-43460, 33-44808, 33-48428, 333-05217, 333-05219, 333-94774, 333-48719, 333-05221, 333-58557, 333-58559, 333-58563, 33-48427, 33-63710, 33-79724, 333-85003, 333-84983, 333-58368, 333-100888, 333-100887, 333-112748, 333-130368, 333-138815 and 333-145323) of Sepracor Inc. of our report dated February 29, 2008 relating to the financial statements, financial statement schedule and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PRICEWATERHOUSECOOPERS LLP

Boston, Massachusetts

February 29, 2008



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**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Adrian Adams, certify that:

1. I have reviewed this annual report on Form 10-K of Sepracor Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 29, 2008

/s/ Adrian Adams

Adrian Adams

*President and Chief Executive Officer*

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, David P. Southwell, certify that:

1. I have reviewed this annual report on Form 10-K of Sepracor Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this annual report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this annual report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this annual report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 29, 2008

/s/ David P. Southwell

David P. Southwell  
*Executive Vice President and Chief Financial Officer*

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report on Form 10-K of Sepracor Inc. (the "Company") for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Adrian Adams, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 29, 2008

/s/ Adrian Adams

Adrian Adams  
*Chief Executive Officer*

A signed original of this written statement required by Section 906 has been provided to Sepracor Inc. and will be retained by Sepracor Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the annual report on Form 10-K of Sepracor Inc. (the "Company") for the period ended December 31, 2007 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, David P. Southwell, Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: February 29, 2008

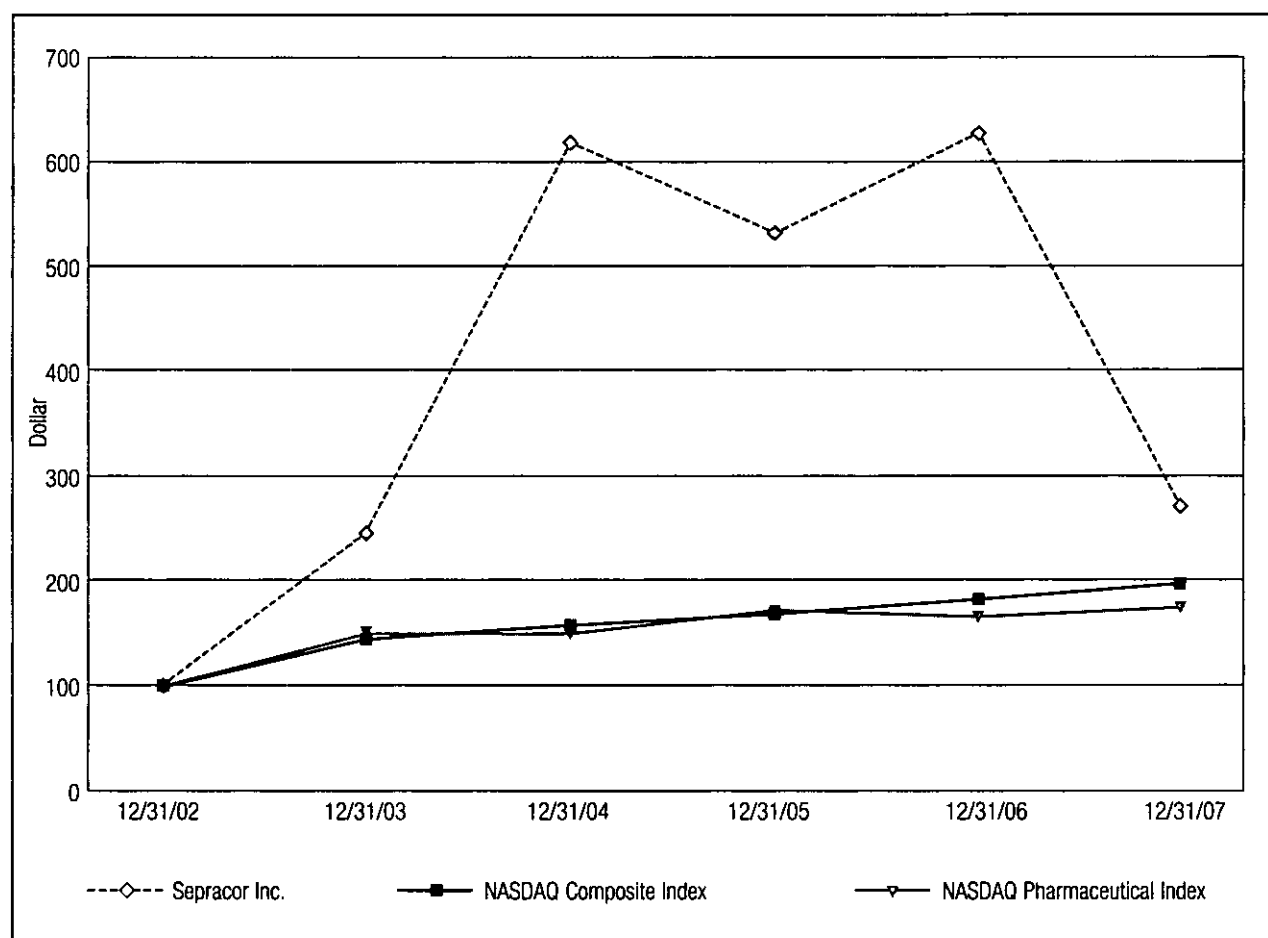
/s/ David P. Southwell

David P. Southwell  
*Chief Financial Officer*

A signed original of this written statement required by Section 906 has been provided to Sepracor Inc. and will be retained by Sepracor Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

## COMPARATIVE STOCK PERFORMANCE GRAPH

The comparative stock performance graph below compares the cumulative stockholder return on our common stock for the period from December 31, 2002 through the year ended December 31, 2007 with the cumulative total return on (i) the Total Return Index for the NASDAQ Stock Market (U.S. Companies), which we refer to as the NASDAQ Composite Index, and (ii) the NASDAQ Pharmaceutical Index. This graph assumes the investment of \$100 on December 31, 2002 in our common stock, the NASDAQ Composite Index and the NASDAQ Pharmaceutical Index and assumes all dividends are reinvested. Measurement points are the last trading days of each of the years ended December 31, 2002, 2003, 2004, 2005, 2006 and 2007.



	12/31/02	12/31/03	12/31/04	12/31/05	12/31/06	12/31/07
Sepracor Inc.	\$100.00	247.50	614.00	533.60	636.80	271.50
NASDAQ Composite Index	\$100.00	149.50	162.70	166.20	182.60	198.00
NASDAQ Pharmaceutical Index	\$100.00	146.60	156.10	171.90	168.30	177.00

## **CORPORATE INFORMATION**

Our Annual Meeting of Stockholders will be held at 9:00 a.m.  
on May 20, 2008 at the offices of WilmerHale, Sixty State Street, Boston, MA.

### **Common Stock**

Our common stock is traded on the NASDAQ Global Select Market under the symbol SEPR.

### **Primary Outside Legal Counsel**

WilmerHale, Boston, MA

### **Independent Registered Public Accounting Firm**

PricewaterhouseCoopers LLP, Boston, MA

### **Corporate Headquarters**

Sepracor Inc.  
84 Waterford Drive  
Marlborough, MA 01752  
Telephone: (508) 481-6700  
Facsimile: (508) 357-7499

### **Transfer Agent and Registrar**

Questions regarding accounts, address changes, stock transfers  
and lost certificates should be directed to:

Computershare  
P.O. Box 43010  
Providence, RI 02940-3010  
Phone: (781) 575-3120

## EXECUTIVE MANAGEMENT

Adrian Adams

*President and Chief Executive Officer*

Mark H.N. Corrigan, M.D.

*Executive Vice President, Research and Development*

Mark Iwicki

*Executive Vice President and Chief Commercial Officer*

Andrew I. Koven

*Executive Vice President, General Counsel and Corporate Secretary*

Robert F. Scumaci

*Executive Vice President, Corporate Finance, Administration, and Technical Operations*

David P. Southwell

*Chief Financial Officer and Executive Vice President, Corporate Planning, Development, and Licensing*



Adrian Adams



Mark Iwicki



Robert F. Scumaci



Mark H.N. Corrigan, M.D.



Andrew I. Koven



David P. Southwell

## BOARD OF DIRECTORS

Adrian Adams

*President and Chief Executive Officer, Sepracor Inc.*

James G. Andress\*

*Former Chairman, Beecham Pharmaceuticals,  
Former President and COO, Sterling Drug Inc.*

Timothy J. Barberich

*Executive Chairman of the Board  
Former Chief Executive Officer, Sepracor Inc.*

Digby W. Barrios

*Former President and CEO, Boehringer Ingelheim Corporation*

Robert J. Cresci

*Managing Director, Pecks Management Partners Ltd.*

James F. Mrazek

*Former Vice President and General Manager,  
Healthcare Division of Johnson & Johnson Products Inc.*

Lisa Ricciardi

*Adjunct Partner, Essex Woodlands Health Ventures*

Timothy J. Rink, MA, MD, ScD

*Former Chairman and Chief Executive Officer, Aurora Biosciences, Inc.*

Alan A. Steigrod

*Former Executive Vice President, Glaxo Holdings plc*

\*Deceased

BROVANA, XOPENEX, LUNESTA and XOPENEX HFA are registered trademarks of Sepracor Inc. OMNARIS is a trademark and ALVESCO is a registered trademark of Nycomed GmbH. Other trademarks or service marks appearing in this report are the property of their respective owners.





Sepracor Inc.  
84 Waterford Drive  
Marlborough, MA 01752

**END**

1074-AR-2008